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The Supreme Court's Decision in *AMG Capital Management v. FTC* – What Does It Mean for FDA Enforcement?

On April 22, 2021, the Supreme Court unanimously held in *AMG Capital Management v. FTC* that the FTC's authority under Section 13(b) of the FTC Act does not grant the agency the right to seek equitable monetary relief such as disgorgement or restitution. As Ropes & Gray previously reported, the import of this decision is that the FTC, in order to obtain monetary relief for unfair and deceptive trade practices, must avail itself of its administrative procedures first under other provisions of the FTC Act and can no longer seek such relief directly through a lawsuit in the federal courts.

Given the similarities between the injunction provisions in the FTC Act and the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Supreme Court's decision likely has significant implications for the government's use of disgorgement and restitution in FDCA injunction cases going forward.

History of Disgorgement and Restitution in FDCA Injunction Cases

The FDCA in a provision entitled "injunction proceedings" grants federal courts jurisdiction to "restrain violations" of the FDCA.[1] Nothing in this provision specifically authorizes the government to seek disgorgement or restitution for violations. However, FDA and the Department of Justice ("DOJ") began pursuing disgorgement or restitution in certain consent decrees of permanent injunction in the late 1990s, arguing that they are equitable remedies that may be imposed in equitable proceedings like injunctions. In FDCA cases, the government has generally used the term "disgorgement" to refer to a defendant's ill-gotten gains being returned to the government, whereas "restitution" refers to those gains being returned to the purchaser. Several high-profile consent decree cases resulted in civil settlements in which the defendants, although they did not admit that their conduct was violative, agreed to significant disgorgement amounts, including, for example, $100 million in a 1999 consent decree with Abbott Laboratories, $500 million in a 2002 consent decree with Schering-Plough, and $175 million in a 2010 consent decree with Genzyme.

The government's authority to seek disgorgement or restitution under the FDCA was challenged in three notable cases in the late 1990s and early 2000s; however, the government prevailed in all three circuit courts of appeal that addressed the issue. Both the Third Circuit, in *United States v. Lane Labs-USA, Inc.*, and the Sixth Circuit, in *United States v. Universal Management Services*, affirmed district courts' grants of restitution.[2] In *United States v. RX Depot, Inc.*, the Tenth Circuit held that the district court had equitable authority to order disgorgement.[3]

Although the government prevailed in these cases, the use of disgorgement or restitution in FDCA injunction cases has remained controversial, and the government has pursued the remedy very infrequently in recent years. When the government has sought equitable monetary relief, it has tended to do so under somewhat novel circumstances in the context of settlements. For example:

- In 2017, the government filed a complaint of permanent injunction against Novo Nordisk, alleging that a drug was misbranded due to noncompliance with Risk Evaluation and Mitigation Strategy requirements. This complaint was unique in that it did not specifically seek any injunctive relief to restrain the defendant's alleged violations; rather, it merely sought disgorgement from the defendant. Under a settlement agreement between the parties, the defendant agreed to pay $12.15 million as disgorgement in exchange for a joint stipulation of dismissal.

- Also, in 2017, the government entered a consent decree of permanent injunction with Philips North America, which restrained the defendant's manufacturing and distribution of certain devices "unless and until" the defendant came into compliance with applicable FDA requirements. The decree included exceptions to these "unless and until" provisions for devices intended for certain purposes (e.g., implementing a correction or removal to reduce an unreasonable risk to health, responding to immediate customer needs for certain devices so that customers can provide adequate patient care). The decree included a prospective disgorgement provision that required the

defendant to pay to the government 30% of net revenues from the sale of devices under these particular exceptions until the defendant had fully satisfied the "unless and until" provisions.

Implications of *AMG Capital Management v. FTC* for the FDCA

The Supreme Court's *AMG Capital Management* decision likely has significant implications for the FDCA because of similarities between the FTC Act and the FDCA in at least two important respects. First, neither the FTC Act nor the FDCA in their respective injunction provisions say anything about equitable monetary relief like disgorgement or restitution. Second, the FTC Act's overall structure is similar to the FDCA in that monetary relief is expressly authorized under other statutory provisions, which suggests that Congress did not intend for the injunction provisions to implicitly provide the authority to seek monetary relief. For example, the FDCA authorizes (i) fines in criminal cases;[4] (ii) civil money penalties for certain violations relating to devices, drug samples, direct-to-consumer drug advertisements, foods, and tobacco products;[5] and (iii) refunds to purchasers of devices posing an unreasonable risk of substantial harm under certain circumstances.[6] Because of these similarities between the FTC Act and the FDCA, a court analyzing the FDCA in light of the holding in *AMG Capital Management* would likely conclude that the FDCA's injunction provision does not authorize retrospective monetary relief.

Going forward, the FDA and DOJ are likely to be even more reluctant to pursue retrospective disgorgement or restitution in any future FDCA cases in order to avoid a definitive court ruling on this issue. However, the government may still consider seeking *prospective* disgorgement in injunction cases along the lines of the 2017 consent decree with Philips North America because, although the issue has not been tested, it is possible that such forward-looking relief may not have been foreclosed by the holding of *AMG Capital Management*.

Assuming that the FDCA does not authorize equitable monetary relief in injunction cases (or, at a minimum, that the government does not wish to test this authority in the courts), the government's ability to obtain substantial civil settlements for alleged FDCA violations may be limited in cases where there is not some other basis for relief, such as the civil False Claims Act. The civil money penalties expressly authorized under the FDCA have caps on the amounts that may be sought both per violation and for all violations adjudicated in a single proceeding. For example, for a violation related to medical devices, the maximum civil penalties that currently may be sought are $28,914 per violation up to $1,927,676 for all violations adjudicated in a single proceeding.[7]

A potential consequence of the government's inability to obtain equitable monetary relief in FDCA injunction cases could be that the government might more frequently pursue criminal cases for FDCA violations in order to obtain the monetary relief that the government believes is warranted. On the other hand, the government's primary concern in a particular case may be seeking remediation of the alleged FDCA violations, rather than a large settlement payment. FDA and DOJ may not feel the need to pursue large settlements in order to deter future violations. A consent decree of permanent injunction, which imposes significant burdens and costs on a defendant, may itself be a sufficient deterrent. In addition, the government would need to weigh the additional burden on its own resources of building a viable criminal case.

We will monitor the impact of *AMG Capital Management* in future FDCA enforcement cases. If you have any questions about this Alert, please contact any member of Ropes & Gray's FDA Regulatory practice or your usual Ropes & Gray advisor.

1. 21 U.S.C. 332(a).
2. *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219 (3d Cir. 2005); *United States v. Universal Mgmt. Servs.*, 191 F.3d 750 (6th Cir. 1999).
3. *United States v. RX Depot, Inc.*, 438 F.3d 1052 (10th Cir. 2006).
4. 21 U.S.C. § 333(a), (b)(1), (e)(3).
5. 21 U.S.C. § 333(b)(2), (f), (g).
6. 21 U.S.C. § 360h(b).
7. 21 U.S.C. § 333(f); 45 C.F.R. § 102.3.