Financial Relationships Likely to Be a Focus in Life Sciences Enforcement and Litigation

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For more than a decade, the Department of Justice (DOJ) has zealously pursued enforcement actions against the health care industry. Given the continued growth in government spending on health care and the billions of dollars in revenue that are paid to the federal government as a result of these cases, we expect this focus to continue. Nevertheless, in recent years we have seen a notable shift in the types of cases that the government is pursuing, away from so-called off-label promotion practices and toward the financial and commercial relationships between health care providers and companies.

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In 2016, we expect DOJ to continue focusing on financial relationships with physicians and that recent DOJ guidance may spur an increased effort to hold individuals criminally and civilly responsible in these investigations. Additionally, the unrelenting flow of *qui tam* lawsuits means federal enforcement agencies will continue to investigate allegations that providers and others submitted false claims for payments to federal health care programs.

Historically, federal criminal and civil investigations have focused on the following types of alleged conduct:

- claims submitted for a service, drug or device that was not medically necessary;
- a health care professional prescribing a service, drug or device based on inducements the manufacturer provided;
- a hospital, managed care organization or pharmaceutical benefit manager including a product on its formulary because of a manufacturer's inducement;
- claims submitted for a drug or device that was promoted for off-label use and where the physician would not have prescribed the product but for that off-label promotion; and
- claims paid for a drug or device based on false or misleading information provided in connection with reimbursement support services.

Financial Relationships With Physicians and Other Health Care Professionals

As in past years, DOJ continues to actively investigate life science companies' financial relationships with physicians and other health care professionals, with particular focus on speaker programs. At least two of the significant pharmaceutical or medical device settlements in 2015 involved allegations of improper inducements through these programs. Of note, the allegations in these cases stretched beyond the question of whether the programs were conducted in exchange for payment and also focused on whether their nature, quality and content were of adequate value for the payment made. Given the likely continued government scrutiny of these relationships, many companies are choosing to enhance their assessments of their speaker programs.

Cooperation and Focus on Individuals

In September 2015, Deputy Attorney General Sally Quillian Yates issued a memorandum (Yates Memorandum) outlining six "steps" prosecutors are required to take when

investigating a company, in order to ascertain whether there are responsible individuals who also should be charged. While the prosecution of individuals is not new, the Yates Memorandum suggests that DOJ is now going further, for example by directing prosecutors to withhold all cooperation credit unless corporations provide all relevant facts about individual(s) involved in alleged corporate misconduct. Recent indictments also demonstrate that DOJ's approach to prosecuting individuals is evolving, for instance by charging individuals with securities fraud in addition to violations of the Food, Drug and Cosmetic Act. It remains to be seen how the Yates Memorandum will affect prosecutors' charging decisions, but it may portend an uptick in prosecutions of individuals, something DOJ and the Food and Drug Administration (FDA) have long threatened. (See "Aggressive Government Enforcement Continues: How Will Individual Prosecutions Impact Activity Against Institutions?")

The Slow Demise of Truthful, Nonmisleading Off-Label Promotion Prosecutions

Despite public statements to the contrary, the court decisions in *United States v. Caronia and Amarin Pharma, Inc. v. United States Food & Drug Administration* appear to have had some impact on DOJ's pursuit of off-label enforcement in cases where there is no evidence of false or misleading statements by a manufacturer. In *Caronia*, the U.S. Court of Appeals for the Second Circuit ruled in 2012 that restricting off-label marketing that was not misleading or untruthful would violate the First Amendment. Following that decision, Amarin sought an injunction specifically allowing off-label promotion, and in August 2015 the district court granted it, ruling that Amarin's statements were truthful and not misleading and thus protected by the First Amendment. (See September 28, 2015, Skadden client alert "The Future of Government Regulation, Enforcement of Off-Label Promotion.") Unless and until other circuits reject the *Caronia* holding, *Amarin* may substantially limit FDA's ability to prohibit truthful and nonmisleading speech outside a product's approved labeling. In addition, there likely will be a steady flow of litigation similar to *Amarin* until FDA issues guidance to the industry that demonstrates its commitment not to engage in regulatory or enforcement actions that necessarily or consequently abridge manufacturers' First Amendment rights. To avoid direct First Amendment challenges, DOJ likely will direct its efforts toward cases with evidence of false and misleading statements. We also expect DOJ and FDA will closely examine a company's conduct rather than its marketing designed to promote a product for an unapproved use.

*For additional information on health care enforcement and litigation trends in the United States and beyond, read "*Getting The Deal Through: Healthcare Enforcement & Litigation*."*