2023 Top-of-Mind Issues for Life Sciences Companies

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The Sheppard Mullin Life Sciences Team decided to take a different approach to our year-end review. We surveyed and considered issues most important to our clients, asking the experts across the various specialties in our Life Sciences Practice the following question: *What do life sciences companies need to keep top of mind in 2023*?

Answers poured in. So many, in fact, that we needed to whittle down this publication. The pieces that remain, however, span the gamut – from the ability of manufacturers to offer drug cost-sharing subsidies to patients to the patchwork of privacy laws popping up across the country to repricing stock options in a bear market. Of course, no annual life sciences publication would be complete without an assessment of enforcement actions over the past year. Be sure to follow our blogs and client alerts throughout the year to see how these top-of-mind topics pan out.

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Pharma and Life Sciences Investigations and Prosecutions: The First Two Years of the Biden Administration

By: Joseph Jay

With the two-year mark of the Biden presidency looming, the administration's approach to prosecuting and investigating entities and individuals in the life sciences industry has begun to present itself with greater clarity. The administration has relied more heavily upon certain civil actions and less heavily upon others as compared to its predecessor. And while prosecution figures have remained steady, the Department of Justice (DOJ) has, like other federal agencies, tailored its enforcement efforts to combatting COVID-19-related fraud while, at the same time, continuing its focus on healthcare fraud of all forms.

False Claims Act Enforcement

The early years of the administration have been marked by a significant uptick in settlements and judgments obtained by the DOJ under the False Claims Act. In February 2022, the DOJ announced that it obtained $5.6 billion in settlements and judgments for the fiscal year ending September 30, 2021, the largest total since 2014 and a more than two-fold increase over the year prior.[1] Of the $5.6 billion in federal losses recovered, more than $5 billion was related to the healthcare industry.[2] In announcing the FCA figures, the DOJ made clear that it was "instrumental" in recovering amounts fraudulently or falsely obtained from state Medicaid programs, which were not included in the $5.6 billion total.[3]

Corporate Integrity Agreements

While FCA settlements and judgments have surged, the last two years have been marked by a decline in the number of Corporate Integrity Agreements entered into the by Department of Health and Human Services Office of Inspector General ("HHS-OIG") to settle federal healthcare investigations. While the HHS-OIG entered into 47 Agreements in 2020, it only entered into 31 Agreements in 2021 and has only agreed to 26 in 2022 as of this writing.[4] This may be explained by open (yet non-public) investigations that have yet to be resolved, or may reflect a conscious decision of the administration to move towards other enforcement actions and tools.

Criminal Prosecutions

During the 2021 fiscal year, United States Attorneys' offices initiated 831 new healthcare fraud investigations and brought criminal charges in 462 cases involving 741 defendants.[5] Additionally, 312 defendants were convicted of crimes relating to healthcare fraud.[6] While these figures do not vary considerably from the year prior,[7] the new administration appears committed to expanding the enforcement efforts against COVID-19-related fraud. In May 2021, Attorney General Merrick Garland formally announced the creation of a COVID-19 Fraud Enforcement Task Force[8] followed by the announcement of a Task Force Director in March 2022.[9] In both 2021 and 2022, the Department brought sweeping enforcement actions against dozens of defendants across multiple federal districts for pandemic-related fraud schemes.[10] Other federal agencies have adopted this COVID-focused regulatory posture, with the SEC bringing enforcement actions and suspending trading in companies for false and misleading COVID-19 related statements.[11] Healthcare fraud remains a target of the Department, with many U.S. Attorney's Offices and the Criminal Division's Fraud Section opening or maintaining healthcare fraud task forces.

Industry Fights Back Against Government Restrictions on Pharmaceutical Manufacturers' Ability to Offer Drug Cost-Sharing Subsidies

By: Dominick DiSabatino and Audrey Crowell

This year, the Office of Inspector General ("OIG") and at least two federal courts have taken a clear stance against pharmaceutical manufacturers' attempts to offer cost-sharing subsidies to Medicare beneficiaries for certain drugs, despite the increasingly creative methods by which these subsidies are being offered. The OIG's stated concerns are: (1) consistently increased risk of fraud, (2) inappropriate usurpation of the legislative function, and (3) price inflation.

However, industry is fighting back. Pharmaceutical manufacturers and lobbying groups are pushing back against these administrative restrictions in an attempt to increase access to life-saving medications.

The Pfizer Saga

In 2019, Pfizer petitioned the OIG regarding its proposed Copay Assistance Programs (the "Programs"). Under the Programs, Pfizer would offer cost-sharing subsidies to Medicare Part D ("Part D") beneficiaries for its medication in one of two ways – (1) through a copay card or coupon provided directly to the patient (the "Direct Copay Assistance Program"), or (2) by funding a 501(c)(3) charity that would provide copay assistance to Part D patients to access Pfizer's drug (the "Independent Charity Program").[12] The OIG maintained that the proposed arrangement would violate the Federal Anti-Kickback Statute (the "AKS").

A. OIG Treatment of Pfizer's Proposed Programs

Although the OIG declined to comment on the legality of the Independent Charity Program, due to an investigation that was pending at the time,[13] the OIG orally informed Pfizer of its determination that the Direct Copay Assistance Program would, in fact, run afoul of the AKS.[14] The OIG reached this conclusion despite the fact that the Direct Copay Assistance Program implemented multiple safeguards to prevent fraud and abuse.[15]

The precise reasoning behind the OIG's conclusion was not made publicly available, but it was consistent with the OIG's long-standing position that pharmaceutical manufacturers' practice of providing cost-sharing subsidies directly to Medicare patients poses "a substantial risk of program and patient fraud and abuse."[16]

B. Pfizer's Response

After exhausting its avenues for agency review, Pfizer filed a complaint in the Southern District of New York, asking the court to issue a declaratory judgment confirming the legality of both proposed Programs.[17] Pfizer challenged the OIG's interpretation on the grounds that (i) the Programs do not implicate the AKS, as Pfizer does not have the requisite intent to defraud; and (ii) the OIG's position, with respect to the Independent Charity Program, raises significant First Amendment concerns as it restricts Pfizer's communications with, and donations to, independent charities that provide assistance to Medicare patients.[18]

In September 2021, the Southern District of New York issued an unfavorable opinion for Pfizer, ruling that (i) Pfizer's Programs would, in fact, violate the AKS; and (ii) the court lacked jurisdiction to determine the First Amendment claim.[19] On appeal this summer, the ruling was upheld by a three-judge panel in the Second Circuit.[20] Most recently, despite the fact that Pfizer's appeal to the U.S. Supreme Court came armed with an amicus brief from the Pharmaceutical Research and Manufacturers of America, the Court, without explanation, decided not to take the case.[21] But the legal battle continues elsewhere in the courts.[22]

OIG's October Advisory Opinion

On October 5, 2022, one week before Pfizer petitioned the Supreme Court, the OIG posted Advisory Opinion No. 22-19 (the "Opinion"), which determined that a proposed arrangement under which pharmaceutical manufacturers would fund, through a nonprofit corporation, cost-sharing subsidies for the manufacturers' own Part D oncology drugs would run afoul of the AKS if the requisite intent were present.

In support of the Opinion, the OIG expressed concerns that the arrangement: (1) circumvents the statutory structure contemplated and implemented by Congress because it purports to replace the current Part D cost-sharing obligations with the manufacturers' cost-sharing subsidies for a large portion of Part D oncology products on the market; (2) poses a risk of inflated healthcare costs because it would remove one of the key pricing

controls of the current statutory framework–exposing beneficiaries to the economic effects of drug prices set by manufacturers; (3) carries the anti-competitive risk of penalizing manufacturers who do not participate because Part D patients would likely be steered away from their products in favor of subsidized products; and (4) poses a risk that prescribers could be dissuaded from prescribing a drug from a non-participating manufacturer, even if not in the patient's best interest.

So, on November 9, the Pharmaceutical Coalition for Patient Access ("PCPA"), the presumed requestor behind the Opinion, filed a lawsuit against the OIG in the Eastern District of Virginia, seeking a declaratory judgment confirming the legality of its cost-sharing program.[23] PCPA's primary arguments mirrored those posed by Pfizer in its 2020 complaint, described above.[24]

Enforcement Trend

Recent administrative opinions and judicial decisions have, not surprisingly, upheld the long-standing position that the AKS is implicated when drug manufacturers provide cost-sharing subsidies ***directly*** to Medicare patients for the manufacturer's own drug. However, these recent administrative opinions and judicial decisions have highlighted a new, targeted enforcement concern – drug manufacturers' provision of cost-sharing subsidies to Medicare patients indirectly through charitable organizations. Readers will recall that, over the past four years, the pharmaceutical industry has provided over $1.5 billion in total DOJ settlements over funding of charities that provide Part D copay support for patients.[25]

As part of this heightened focus on manufacturers' indirect provision of cost-sharing subsidies, the OIG's October Opinion clarifies and expands upon a 2005 OIG Bulletin, which acknowledged the possibility of a "coalition model" to increase accessibility to certain drugs for financially-needy Part D beneficiaries.[26] Although the 2005 Bulletin discussed several safeguards that might limit the risk of AKS liability for coalition models, the OIG has now concluded that the coalition model still encompasses too high a risk of fraud. This recent clarification of the 2005 Bulletin is especially significant because both Pfizer's 2020 complaint and PCPA's 2022 complaint lean on the 2005 Bulletin as justification for the proposed cost-sharing arrangements.

Takeaways

Recent administrative discourse and enforcement actions scrutinizing cost-sharing subsidies provided indirectly through charitable organizations have focused on the direct tie between manufacturers' placement of funds with the charitable organization and the direct pass-through of those funds to patients to cover Part D cost-sharing obligations for the manufacturers' own products. Especially given the OIG's unwillingness to work with Pfizer in crafting a structure that might comply with the AKS, it seems that the OIG, and now federal courts, will continue to prohibit pharmaceutical manufacturers from providing cost-sharing subsidies to Medicare patients through charitable organizations unless the donations to these charitable organizations are made without strings attached.

The decisions made by the OIG and the Second Circuit stand tantamount to a strict liability standard for the AKS. For that very reason, pharmaceutical manufacturers launched litigation on this pivotal issue. Despite Pfizer's setback in the U.S. Supreme Court, if the Fourth Circuit decides differently, the door may still be open for the pharmaceutical industry to realize a complete change in the scope of cost-sharing subsidies that they may legally provide to Medicare patients, especially those subsidies delivered through charitable organizations. There is no doubt that 2023 will continue a hot trend in this space.

Repricing of "Out of the Money" Stock Options

By: Jeffrey Fessler and Seth Lemings

Overview

Engaging and retaining key employees is a central concern for emerging companies in the biotechnology and life sciences field. However, lack of available cash often serves as a barrier to hiring the right people to take the company to the next level. In order to incentivize performance, increase retention and maintain a competitive compensation program, life sciences companies frequently grant stock options to directors, executive officers, other employees and service providers.

Typically, when stock options are granted, the exercise price of the options will be equal to the current trading price of the shares of common stock underlying the options. The excess of the current trading price of the shares of common stock underlying such stock options as measured against the exercise price of the stock options represents the profit that can be made by the holder of the option.

Conversely, when the exercise price of a stock option is higher than the current trading price of the shares of common stock underlying the stock options, the stock option is said to be "underwater" or "out of the money." In such a situation, stock options no longer retain their traditional benefits because the holder of the option is not able to generate a profit by exercising the option and selling the underlying shares.

In addition to the loss of traditional benefits, stock options that are "out of the money" can pose additional problems, including:, (i) causing an "overhang" of equity, and (ii) hindering the issuance of additional equity instruments by the company.

Life Sciences Bear Market

Recently, national stock markets have experienced sustained periods of volatility and unpredictability for many reasons – including, among others, the COVID-19 pandemic, the Russian invasion of Ukraine, historically significant levels of inflation, and political and social issues.

Life sciences companies, in particular, have been in a bear market for close to two years now. The volatility and unpredictability of the stock market has caused the stock prices of many publicly-traded life sciences companies to decline rapidly, resulting in an increasing number of stock options that are out of the money. Companies that have issued stock options that are now "out of the money" may consider repricing them in order to restore the traditional benefits of stock options that have been lost. This article is intended to serve as a resource for companies that are listed on the New York Stock Exchange (NYSE) or The Nasdaq Stock Market (Nasdaq) which may be considering repricing stock options that are "out of the money."

Solutions for Underwater Stock Options

A publicly-traded company that is evaluating whether to reprice its underwater stock options should keep in mind the following issues:

- Is stockholder approval required for an option repricing?
- Which of the below repricing methods is most appropriate?
- Which stock option holders will participate in the repricing?
  - How do U.S. Securities and Exchange Commission ("SEC") tender offer rules and SEC disclosure requirements apply to a potential stock option repricing?
  - Is the company able to implement a stock option repricing under the terms of its equity plan?

Alternative Methods of Repricing

One-for-One Repricing (Straight Option Repricing)

The company unilaterally (i) amends underwater stock options to lower the exercise price to the current market price of the underlying stock, or (ii) cancels underwater stock options and replaces them, on a one-for-one basis, with stock options having a reduced exercise price.

Pros +	Cons –
• Easily communicated and understood by stock option holders (assuming no other changes to the stock option terms) • Allows stock option holders to maintain control over the taxable event (i.e., tax at exercise) • Not likely to trigger SEC tender offer rules or require stock option holder consent	• Often considered a "windfall" for stock option holders and likely to face stockholder resistance because stockholders do not benefit from the same treatment as stock option holders. • NYSE and Nasdaq require listed companies to obtain shareholder approval of option repricings, unless the plan specifically permits repricing. However, most forms of equity plans would require shareholder approval • Likely to face negative recommendations from proxy advisory firms unless (i) vesting is changed to include additional requirements, (ii) the exercise price is reset to the current market price or a premium to the current market price (thereby causing the options to remain out of the money), or (iii) directors and officers are not eligible for the repricing • Repriced stock options remain susceptible to going underwater in the future

Option-for-Option Exchange (Value-for-Value Exchange)

Underwater stock options are replaced with new stock options that are exercisable for a smaller number of shares with an exercise price equal to the current fair market value of the underlying stock. The exchange occurs on a "value-for-value" basis, where the value of the exchanged stock options, based on a commonly accepted valuation method (e.g., Black-Scholes or binomial lattice model), is equal to, or less than, the value of the underwater stock options being cancelled, resulting in an exchange ratio of less than one-to-one. The newly issued options will typically have a different vesting schedule than that of the prior underwater options. Directors and officers will usually be ineligible for such a repricing in order to avoid the appearance that management is sheltered from declines in stock price while other shareholders are not.

Pros +	Cons –
• Allows stock option holders to maintain control over the taxable event (i.e., tax at exercise) • Viewed more favorably by institutional stockholders and proxy advisory firms than a one for-one exchange • Reduces dilution and equity overhang and preserves the equity plan's share reserve • Avoids an accounting charge if the value of the new stock options is equal to or less than the value of the exchanged underwater stock options	• More difficult for stock option holders to understand than a one-for-one exchange and may require more employee communication efforts • Requires shareholder approval unless the plan specifically permits repricing. However, most forms of equity plans would require shareholder approval • Requires determination of proper exchange ratio to use • Will likely trigger SEC tender offer rules • Repriced stock options remain susceptible to going underwater

Option-for-Cash Exchange

Cancellation of underwater stock options in exchange for cash based on a Black-Scholes or similar valuation technique.

Pros +	Cons –
• Reduces issued equity overhang and preserves share reserve under the equity plan • Easily explained and understood by employees • Eliminates the possibility of future underwater stock options • Provides immediate value to participants • Shareholder approval is not required	• Requires determination of proper exchange ratio to use • Immediately taxable upon payment Will likely trigger SEC tender offer rules • Requires a cash outlay, which may not be prudent for a company looking to conserve cash • The long-term incentive and retention features of equity awards are lost • May present a number of tax related issues unless done in a very careful manner.

To determine which stock option repricing method will be most beneficial, a company will need to consider: (1) its compensation philosophy, (2) what it hopes to achieve through a stock option repricing, (3) alternatives available under any equity plans, and (4) the company's cash on hand. The one-for-one, option-for-option and option-for-stock methods are most common. The option-for-cash exchange is much less common – especially in situations of volatility where a company may need to retain cash. Given the views of proxy advisory firms and institutional stockholders, a value-for-value stock option repricing in the form of either an option-for-option or option-for-stock exchange is likely to be the best repricing method for public companies.

Considerations For Companies Contemplating Stock Option Repricings

Participation in the Stock Option Repricing

Proxy advisory firms strongly disfavor director and officer participation in stock option repricings. Because of this, if stockholder approval is required, companies should decide whether to exclude directors and officers from participating in the option repricing.

Terms of Replacement Stock Options

If new stock options are issued in place of existing underwater stock options, the company must consider whether such new options will retain the same vesting terms or whether additional vesting terms and conditions will be imposed.

Cancelled Stock Options or Shares

Companies should confirm whether their equity plans allow for cancelled stock options or shares to be returned to the plan's share pool for future issuances. Additionally, companies may choose to permanently retire any cancelled shares because such retirement will increase the likelihood of receiving proxy advisory firm support and stockholder approval.

Actions Requiring Stockholder Approval

NYSE and Nasdaq listing rules require stockholder approval for any stock option repricing unless a company's equity plan expressly permits repricing without stockholder approval. Companies should review their equity plans to determine whether such a provision is included. Often, companies' equity plans do not permit stock option repricings without stockholder approval because institutional stockholders and proxy advisory firms prefer that stockholders have approval rights of such actions.

Unless allowed by a company's equity plan, the following repricing actions are considered material amendments that require stockholder approval under NYSE and Nasdaq rules:

- Reducing the exercise price of a stock option after it is granted;
- Canceling stock options and issuing replacement equity awards when the exercise price of the original options exceed the fair market value of the underlying stock, unless such cancellation and exchange occurs in connection with a merger, acquisition, spin off or other similar corporate transaction;
- Any other action treated as a repricing under generally accepted accounting principles (e.g., the grant of replacement stock options close in time to the cancellation of underwater stock options).

Under NYSE and Nasdaq listing rules, stockholder approval is not required for the cancellation of underwater stock options in exchange for cash. However, many equity plans prohibit cancellation of underwater stock options for cash without stockholder approval because proxy advisory firms consider it be a "problematic pay practice."

SEC Tender Offer Rules

SEC tender offer rules apply when the holder of a security must make an investment decision with regard to the purchase of a new security or the modification or exchange of an existing security for a modified or new security. A one-to-one repricing of stock options which results in a lower exercise price will generally not trigger SEC tender offer rules because there is virtually no investment decision required. However, a value-for-value exchange implicates tender offer rules because stock option holders must decide whether to accept a new option to purchase fewer shares or to exchange their existing stock options for other forms of equity awards or cash. Additionally, the SEC considers a repricing of stock options requiring the consent of stock option holders to be a self-tender offer by the issuer of the stock options.

Digital Health & Telehealth – A Patchwork of Privacy Laws Continues

By: Allison Fulton, Julia Kadish and Arushi Pandya

In many instances, digital products are not squarely regulated by the US Food and Drug Administration (FDA), or by the Department of Health and Human Service (HHS) Office of Civil Rights (OCR)—which enforces the Health Insurance Portability and Accountability Act (HIPAA). Instead, a patchwork of various state data privacy and security laws may apply, in addition to consumer protection laws. We expect to see states continue to pass laws, which means companies have to monitor state law developments to ensure the data they collect meets regulatory requirements.

Widespread Adoption of Telehealth – The Impact of Covid-19

The commercialization of digital health and medtech products, specifically, telehealth tools, has significantly increased over the past several years — accelerated, in part, by the COVID-19 Public Health Emergency (PHE). Understanding the need to allow flexibility for innovative solutions, federal regulators implemented various waivers aimed at enhancing access to patients and physicians. These waivers, along with consumer demand, spurred the use of telehealth technologies during the course of the PHE.

Although COVID-19 waivers are set to end upon the termination of the PHE, their impact persists. The industry's use of PHE waivers signals a continued trend toward flexibility and innovation. This trend will likely result in changes to existing regulations, or at the least, agency guidance that provides flexibility in enforcement of existing regulations. As evidence of the industry's desire to make telehealth the new norm, a group of over three hundred healthcare and industry organizations issued a letter to Congress in January 2022 titled "Establishing a Pathway for Comprehensive Telehealth Reform," which outlined the need to prioritize telehealth going forward.[27] The letter also proposed several potential steps to continue telehealth flexibility after the PHE, including enacting legislation to support the use of telehealth.

Telehealth and MedTech – A Patchwork of Privacy Laws

HIPAA – And Its Limited Application

While many developers (and users) of digital health products and services may think of the Health Insurance Portability and Accountability Act (HIPAA) as a primary regulatory consideration for their product, in actuality, HIPAA does not, in fact, regulate the privacy and security of all health information on a whole. Rather, it applies under fairly narrower circumstances.

HIPAA is a federal law that protects the privacy and security of individually identifiable health information (protected health information or PHI). However, HIPAA only governs "covered entities," which is defined as health plans, health care clearinghouses, health care providers that electronically transmit claims, and "business associates," which are persons or entities that perform certain functions or activities that involve the use or disclosure of PHI for a covered entity.[28] In many cases, medtech and digital health companies are neither "covered entities," nor "business associates" under HIPAA, and therefore fall outside of its jurisdiction. This is the case, even if the products generate and store consumer health-related data. There are exceptions, of course, and the analysis of whether HIPAA applies depends on the data flows and how services are paid. But generally speaking, health information accessed through or stored on consumer cell phones or tablets, including geographic location information or search history, are not protected under HIPAA.[29]

Unfair and Deceptive Trade Practice Laws (UDAAP): The FTC and State Laws

In addition to FDA and HHS's OCR (which enforces HIPAA), the Federal Trade Commission (FTC) is a major federal player in the regulation of telehealth. Because FTC laws are generally applied to consumer products and services, the FTC Act applies regardless of whether a product meets the definition of a medical "device" under FDA laws, or whether collected information is defined as PHI under HIPPA.

The FTC Act broadly prohibits "unfair and deceptive acts or practices" in or affecting commerce.[30] Many states have consumer protection laws that either overlap with this federal law or impose additional requirements. Many of these state UDAAP equivalent laws provide a means for affected consumers to file class action lawsuits against digital health companies.

Federal and state UDAAP laws are used as the basis for many privacy and data security-related enforcement actions and lawsuits. Allegations under UDAAP laws are based on a company not doing what it said it would do with personal information (deception). Cases in this area are successful if the plaintiff can show that there were misrepresentations or omissions of material facts in statements made about how information would be used, or that a company had insufficient security measures in place, and thereby, engaged in fundamentally unfair practices.

More State Privacy and Data Security Laws

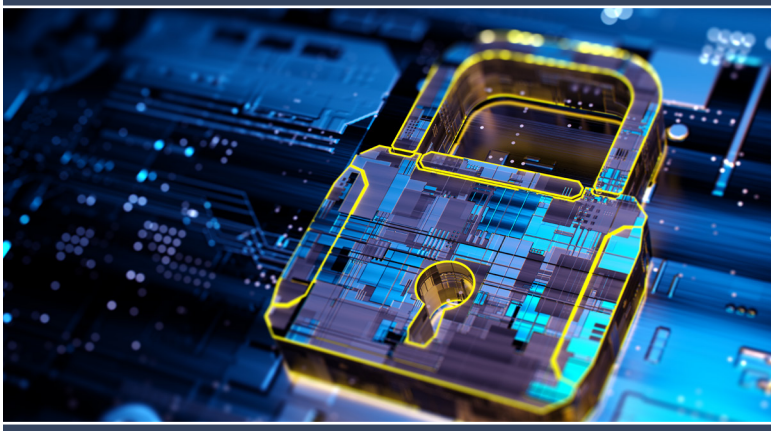
The states have created a patchwork of privacy and security laws that directly impact how a company can collect and use information, as well as, obligations with respect to providing individual "rights"--i.e., access, opting out, and deletion. At least 22 US states have laws that require companies to protect information.[31] This includes states such as Colorado, Connecticut, Maryland, Massachusetts, Oregon, New Jersey, and New York.

The state laws may apply to organizations based on certain types of information that it collects, and/or because a company collects information from residents of the impacted state. Some of these state laws contemplate that specific requirements be addressed in a data security program (*e.g.*, written information security policy, vendor contractual requirements, employee training, a designated person in charge, etc.), while others generally require that "reasonable security" measures be deployed.

For example, the current state law in California (along with its recent amendments) and Virginia, and those other state laws coming into effect in 2023 in Colorado, Connecticut, and Utah should be top of mind for digital health companies.[32] Companies subject to Colorado, Connecticut and Virginia laws will need to obtain consent for collecting any "sensitive information,"[33] such as medical histories or information about a mental or physical condition.[34] California or Utah laws require an opt-out right to the processing of sensitive information.[35] Additionally, there are a number of other state laws that may apply to digital health companies. The applicability of such laws depends on: (1) the type of information the company collects (*e.g.*, biometric, genetic), (2) from whom the company collects such information (e.g., children), and (3) how the company communicates with such individuals (*e.g.*, calling, emailing, texting).

What's Next for Telehealth & Privacy

Telehealth and remote patient access is the new norm. We expect states will continue to enact laws to fill the perceived gaps in federal regulations. With the myriad of potential privacy and data security laws, and those on the horizon, many companies will want to think about putting into place a principles-based privacy program that is aligned with an organization's underlying mission and goals. A customized program, focusing on the core elements found across data privacy laws (*e.g.*, notice, individual rights, choice, vendor management, etc.) enables companies to have a more nimble approach for adapting to this changing area of law.



Enforcement Highlights – 2022

By: Eve Costopoulos

I. Refinement of Corporate Criminal Enforcement Principles by Department of Justice

This year, the Department of Justice (DOJ) continued to reaffirm the importance of its June 2020 Evaluation of Corporate Compliance Programs, June 2020 guidance (DOJ Guidance)[36] and to further announce important new initiatives that increase the accountability of both corporations and individuals alike. The new initiatives provide corporations and individuals with incentives, such as avoidance of prosecution, reduced fines and penalties, and no imposition of corporate monitor when they take appropriate steps to maintain an effective compliance program.

In March, the Department of Justice (DOJ) Criminal Division announced that, moving forward, the DOJ was considering, whether all corporate criminal settlements, including guilty pleas, deferred prosecution agreement and non-prosecution agreements, should require Chief Executive Officers (CEOs) and Chief Compliance Officers (CCOs) to certify the effectiveness and functionality of the ethics and compliance program at the end of any agreement term. In a speech at the ACAMS 2022 Hollywood Conference, Assistant Attorney General Kenneth A. Polite Jr. articulated that the goal of the certification requirement was not punitive, but rather, intended to empower companies, and especially CCOs, by placing them in a truly independent role with appropriate authority, power and stature within the company to ensure that the company has an ethical and compliance focused environment.[37]

In September, DOJ announced more revisions to its existing corporate criminal enforcement policies and practices through a memorandum titled "Further Revisions to Corporate Criminal Enforcement Policies Following Discussions with Corporate Crime Advisory Group" ("DOJ Memorandum").[38] The principles articulated in the DOJ Memorandum confirm: i) that corporate criminal enforcement remains one of DOJ's enforcement priorities with respect to how prosecutors should ensure individual and corporate accountability, and ii) that DOJ expects companies to be regularly assessing the effectiveness of their compliance programs, in order to identify and remediate non-compliant activities, and to self-report corporate wrongdoing when appropriation.

The DOJ Memorandum emphasized the following principles:

- **Individual Accountability** – Ensuring accountability for individuals who commit and profit from corporate criminal activities remains a top priority for DOJ.

- **Corporate Accountability** – Determining a corporation's culpability for criminal conduct will include a review by DOJ of a corporation's history of misconduct to assess whether the misconduct may be interpreted to indicate broader or systemic weaknesses in the corporate compliance program.

- **Voluntary Self-Disclosure and Cooperation** – Incentivizing companies to self-report and timely resolve misconduct and provide full disclosure to and full cooperation with DOJ is of paramount importance, and the efforts taken by companies to do so will influence DOJ's determination of whether or not to impose an independent monitor.

- **Self-Assessment** – Assessing the strength of a corporation' s existing compliance program against published criteria such as the DOJ Guidance is something that DOJ expects from companies looking to avoid penalties. DOJ indicates that it will place renewed emphasis on whether the company has: (i) implemented compensation systems to incentivize compliance and financially penalize misconduct, (ii) incorporated clawback provisions into employee agreements, and (iii) adopted effective policies and training program around employee use of company data on personal devices and third party messaging platforms to ensure that business-related electronic data and communications are preserved.

- **Use of Monitors** – On a case-by-case basis, DOJ will assess the need for independent monitors, evaluating such things as the corporation's cooperation, its history of misconduct (including, prior criminal, civil, and regulatory resolutions, both domestically and internationally), whether the corporation voluntarily disclosed information to DOJ, and the frequency of testing of its compliance program to identify weaknesses.

The DOJ Memorandum sends a clear message to corporations and their management teams that going forward, it will continue to pursue aggressive enforcement against both criminal corporate conduct and criminal conduct committed by individuals. In response, companies and their CCOs should be diligent about regularly reviewing and documenting their compliance programs through auditing and monitoring activities. Additionally, companies should ensure that:

- its corporate risk profile is updated to meet changing business activities and regulatory requirements;
- misconduct is quickly identified and adequately remediated;
- compensation systems incentivize individuals to engage in compliant behavior; and
- there is executive oversight of the company's compliance programs.

By utilizing the principles articulated in the DOJ Memorandum, as well as in previous DOJ pronouncements, companies can identify and control behaviors that might otherwise create long-term risks for them.

II. Select Enforcement Actions

The settlements discussed below are representative of the type of enforcement actions pursued by DOJ during 2022. They indicate a continued focus by DOJ on (i) the activities of pharmaceutical and device manufacturers and their employees who engage in criminal conduct, (ii) the provision of kickbacks by manufacturers to incentivize recipients to either prescribe or purchase drugs or medical devices, and (iii) the recipients who receive those kickbacks and who submit false claims to government healthcare programs. The settlements also affirm the power that a whistleblower has to actually pursue fraud claims against manufacturers and the receptiveness of the DOJ to those claims. We believe that these settlements are representative of the cases that DOJ will continue to pursue in 2023.

A. *United States ex rel. Bawduniak v. Biogen Idec, Inc.* - DOJ continued its scrutiny of speaker programs and other similar transfer of value arrangements between pharmaceutical and device manufacturers and healthcare providers, building upon prior settlements involving speaker programs[39] as well as the issuance of the OIG Special Fraud Alert: Speaker Programs, November 2020 (SFA).[40] DOJ's most noteworthy enforcement action was embodied in the $900 million settlement reached with Biogen, resolving a lawsuit filed by former employee Michael Bawduniak (Plaintiff) against Biogen Inc. (Company) under the *qui tam* provisions of the federal False Claims Act.[41] Under the terms of the settlement, the Company agreed to pay $843,805,187 to the United States and $56,194,813 to fifteen states. The Plaintiff received approximately 29.6% of the federal proceeds from the settlement or $250 million.

   The complaint accused Company of paying millions of dollars in kickbacks to healthcare providers (HCPs) to induce them to prescribe the Company's multiple sclerosis (MS) drugs from Jan. 1, 2009 through March 18, 2014.[42] The kickbacks took the form of speaker honoraria, speaker training fees, consulting fees and excessive meals that were provided to HCPs who attended these company events. These activities were offered as inducements to approximately 1000 influential HCPs, who had been identified as "high prescribers," and who were responsible for writing approximately 60% of prescriptions for the MS market.

- **Consulting** – Company entered into hundreds of consulting agreements with "high prescriber" HCPs to obtain market research regarding its MS drugs, even though it had no demonstrable need for the information and many of the HCPs were not qualified to provide the market research. HCPs attended multiple consulting events.

- **Advisory Board meetings** – Company engaged hundreds of HCPs to participate in advisory meetings across the country at luxury locations to provide marketing input on an unapproved investigational drug, asking many similarly situated and experienced HCPs the same questions. Company paid the HCPs based upon criteria that measured their ability to influence the prescription of MS treatments.

- **Speaker Training** – Company repeatedly trained hundreds of HCP speakers on Avonex and Tysbari, paying them for these trainings even though most speakers only presented once or twice a year. In some instances, speakers presented to a single attendee at a speaker program. These speakers were selected based on their prescribing ability, and not on their speaking ability.

- **FMV** – Company paid more than fair market value (FMV) for HCP services and attendance at meetings, often disregarding its own internal FMV tiering criteria and internal annual caps on payments to HCPs. The Company also ran "return on investment" analyses on the aggregate payments made to HCPs.

The complaint also alleged that the Marketing Department routinely circumvented the Compliance Department by ignoring requests from the Compliance Department for an annual consulting plan and disregarded Compliance concerns that there were too many duplicate meetings, too many consultants providing the same consulting services and too many payments being made to HCPs.

The Biogen settlement is significant for a number of reasons. First, it is a reminder of the continuing fraud and abuse concerns the DOJ has with manufacturer-sponsored speaker programs, which programs often involve payments and other transfers of value to providers in a position to prescribe those manufacturers' products (as discussed in detail in the SFA) and which implicate the Federal AntiKickback Statute (AKS).[43] Second, it is a reminder that manufacturers need to implement effective compliance programs to actively address priority issues impacting the business. Last, given the size of the award to the Plaintiff (reported to be the highest whistleblower award under any government program), it is an indication that companies are vulnerable to individual whistleblowers who may be able to pursue litigation on their own and win substantial rewards—although the efforts to do so require significant resources and commitment on their part.

As a result, companies should revisit the SFA and ensure that their speaker program activities conform with the criteria set forth therein. Companies should also consult the personal services safe harbor regulations of the AKS to ensure that their consulting arrangements with HCPs meet the specific requirements necessary to ensure that they are not implicating the AKS. Further, Companies must ensure that their whistleblower program and investigative process is implemented and documented appropriately.

Companies should also carefully consider how they plan, organize, execute and evaluate HCP consulting operations using commercial analytics, as these activities — often as precursors to commercial activity — lay the groundwork for potentially problematic marketing activities in the future. Targeting "centers of excellence" or "academic centers" may, on its face, appear as legitimate criteria for selecting HCPs for consulting activities. However, companies should ask themselves whether that methodology is just subterfuge for targeting high prescribers, who tend to gravitate toward or practice within those centers. Similarly, commercial teams should take a careful look at internal segmentation analyses, as well as how those analyses are documented internally, to ensure that legitimate business rationales are not undermined by the way in which HCP segments are referenced.

The complaint talks about targeting and segmenting on "product loyalty," so teams should ensure that decisions on consulting are not tied in any way to decisions about whether a particular HCP is a high prescriber or not. And of course, careful consideration should always be paid on conducting any kind of ROI analysis on HCP consulting expenditure.

B. *United States v. Deepak Raheja, Gregory Hayslette, Frank Mazzuco, and Bhupinder Sawhny* - In another recent settlement involving speaker engagements, Dr. Deepak Raheja and Frank Mazzucco pled guilty on Oct. 31, 2022, to their roles in a pharmaceutical kickback conspiracy in which Raheja, a licensed Ohio physician, wrote prescriptions for a drug to patients that did not have the indicated condition in exchange for money and other items of value. Raheja and Mazzucco both pled guilty to one count of conspiracy to solicit, receive, offer and pay health care kickbacks. As part of the terms of the plea agreement, Raheja agreed to a sentence of 30 months in prison, surrendered his medical license, and was ordered to pay at least $1,178,460.40 million in restitution and a fine to be determined. Raheja is scheduled to be sentenced on Feb. 3, 2023, and Mazzucco is set to be sentenced on Feb. 15, 2023.[44]

   Mazzucco was employed by Avanir Pharmaceuticals (Avanir) as a regional business manager supervising pharmaceutical sales representatives. Avanir manufactured Nuedexta, a drug approved by FDA to treat pseudobulbar (PBA). The complaint alleged that Mazzucco and other codefendants conspired together to increase the number of prescriptions Raheja and other co-conspirators wrote for Nuedexta in exchange for the payment of monetary kickbacks and other items of value. The incentives included arranging speaker's bureau programs, which were mostly social events; honoraria payments; the falsification of sign-in sheets from speaking engagements to maximize payments; and providing food and beverages to doctors and their office staff.

   In return for the incentives, Raheja and the other codefendants wrote more Nuedexta prescriptions by falsely diagnosing patients with PBA and recording fictitious symptoms in patient records to support a diagnosis of PBA, thereby causing the submission of billings to Medicare and Medicaid for Nuedexta prescriptions for patients that did not have PBA.[45]

C. *U.S. v. Dunn Meadow* - The DOJ also continued to prosecute illegal kickback schemes carried out among pharmacies, prescribers and manufacturers. In August,

the DOJ announced that Dunn Meadow LLC (Dunn Meadow), a New Jersey pharmacy, admitted its role in a conspiracy to illegally distribute prescription opioids in violation of the Controlled Substances Act (CSA) and to give kickbacks to health care providers and pharmaceutical company sales representatives in violation of the AKS, which incentives took the form of lunches, dinners, happy hours and entertainment, to induce them to send certain opioid prescriptions to Dunn Meadow to fill.[46]

Dunn Meadow admitted that its violations of the statute caused a loss to federally funded healthcare programs of over $4.5 million and further agreed to pay up to $50 million generated from future revenue to resolve the civil claims brought against it. In addition to violations of the CSA, the government alleged Dunn Meadow received remuneration from at least one pharmaceutical manufacturer in the form of payments for "shipping fees," although the pharmacy routinely shipped medications without manufacturer payment.

D. *US v. Respironics, Inc., et al.* – In yet another lawsuit initiated by a whistleblower, Philips RS (formerly Respironics), a manufacturer of durable medical equipment paid $24 million to resolve False Claims Act violations.[47] The lawsuit alleged that Philips paid kickbacks to its Durable Medical Equipment (DME) suppliers to increase their purchases of Philips ventilators, oxygen concentrators, and other respiratory-related medical equipment. In turn, the DME suppliers billed Medicare and Medicaid for the equipment purchased from Philips. The kickback provided by Philips was Hospital Management Systems (HMS) prescription data that Philips purchased from a third party. The HMS data detailed the prescribing data of specific doctors by geographic region and further showed which DME suppliers were filling orders prescribed by each doctor. In the hands of the DME suppliers, the data provided a roadmap of physicians they could target to market their products and services.[48]

Philips agreed to pay $24 million to resolve the False Claims Act violations. Philips also entered into a five-year Corporate Integrity Agreement with HHS-OIG that requires Philips to implement a robust compliance program that includes review of arrangements with referral sources and monitoring of its sales force. The CIA also requires Philips to retain an independent monitor, selected by the OIG, to assess the effectiveness of Philips' compliance systems. The whistleblower was awarded $4.3 million dollars of the federal settlement amount.

E. *U.S. vs. Bayer Corporation* – In another settlement that was prompted by two separate whistleblower complaints, Bayer Corporation[49] agreed to pay $40 million to resolve False Claims Act and False Statement violations arising from the drugs Trasylol, Avelox and Baycol. The two lawsuits were filed by Laurie Simpson (Simpson), a former marketing employee. Simpson had pursued the allegations against Bayer for almost two decades and she was awarded $11 million from the settlement.[50] In one lawsuit, it was alleged that Bayer paid kickbacks to hospitals and physicians to increase use of two drugs Trasylol (used to control bleeding in heart surgeries) and Avelox (an antibiotic), by marketing these drugs for off-label uses to patients, misrepresenting both their safety and efficacy. The kickbacks included all-expense paid consulting trips throughout the United States, excessive consulting fees, grants and other gifts.

As a result, it was alleged that Bayer caused the submission of false claims to federal health programs related to the products. Subsequently, Trasylol and Baycol were withdrawn from the market for safety reasons. In its announcement of the settlement, the DOJ noted the important role that whistleblowers play in identifying fraud in federal healthcare programs.

CMS and Senate Heighten Oversight of Marketing Practices in Medicare Programs

By: Christine Clements and Sheela Ranganathan

The Medicare Advantage program continues to grow in popularity among seniors. In 2022, more than 28 million people - nearly half of all Medicare beneficiaries - are enrolled in a Medicare Advantage plan rather than Original Medicare.[51] Forty-nine million Medicare beneficiaries receive prescription drug coverage under Medicare Part D, with more than half of those individuals receiving their Part D coverage through a Medicare Advantage plan.[52] Despite the popularity of these plans, the Centers for Medicare and Medicaid Services ("CMS"), which administers Medicare, has seen an increase in complaints by Medicare beneficiaries and their caregivers about the marketing practices of Medicare Advantage organizations ("MAOs") and Part D sponsors and third parties that solicit leads and/or enrollments on behalf of MA and Part D plans. These complaints have also caught the attention of the Senate Finance Committee. As a result, the sales and marketing practices of MAOs and Part D sponsors, healthcare providers that participate in these plans, and third-party marketing organizations, are experiencing increased regulatory oversight.

On May 9, 2022, CMS issued the final rule on Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (the "Final Rule").[53] The Final Rule, among other changes, establishes new requirements for MAOs, Part D sponsors and third-party marketing organizations or "TPMOs." CMS defines a TPMO as: "organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of a [MA or Part D] plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § [422.2 or 423.4], but may also be entities that are not FDRs but provide services to [an MA plan or a Part D sponsor] or [an MA plan's or a Part D sponsor's] FDR."[54]

Under the Final Rule, MAOs and Part D sponsors must require their TPMOs to use a standardized disclaimer on their website and marketing materials, including all print materials and television advertising that meet the definition of marketing.[55] Under § 422.2260, marketing means communications that meet certain standards for intent (draw a beneficiary's attention to a MA plan or plans; influence a beneficiary's decision-making process when making a MA plan selection; and influence a beneficiary's decision to stay enrolled in a plan), and also include or address the plan's benefits, benefits structure, premiums, or cost sharing, measuring or ranking standards, or rewards and incentives as defined under § 422.134(a). Thus, the Final Rule's TPMO disclaimer applies to a broad range of materials and activities.

Finally, CMS also requires MAOs and Part D sponsors to heighten oversight of TPMOs by ensuring that TPMOs make necessary disclosures, record all calls with beneficiaries, and report any staff violations.[56]

Also, in response to complaints about deceptive marketing practices related to Medicare plans, CMS has been conducting "secret shopping" by calling numbers associated with television advertisements, mailings, newspaper advertisements, and internet searches to monitor the beneficiary experience.[57] Through this investigation, CMS found that some agents were not complying with current regulations. For more than 80% of the calls reviewed, agents failed to provide the beneficiaries with the necessary information or provided inaccurate information to make an informed choice. As a result of these findings, CMS released Frequently Asked Questions ("FAQs")[58] and a memo ("Memo")[59] on best practices for marketing activities during the 2023 Annual Election Period ("AEP") running from October 15, 2022 through December 7, 2022, focusing on TPMOs.

The FAQs discuss both requirements related to recording calls between beneficiaries and TPMOs and requirements related to the TPMO disclaimer. Of note, the FAQs confirm that all calls between a TPMO and a beneficiary must be recorded, with no exceptions. They also clarify that the TPMO disclaimer is required in all marketing materials, including social media posts, unless the materials were developed by the plan (such as a Summary of Benefits) and the agent is using them exactly as provided by the plan.

The Memo discusses 42 C.F.R. §§ 422.2261(b)(3) and 423.2261(b)(3), which provide that CMS may accept certain types of marketing materials through its File &Use framework rather than requiring CMS approval before use. Though CMS had previously designated television advertisements as a marketing material that qualifies for File & Use, the Memo states that no television advertisements will qualify for such flexibility beginning January 1, 2023. As a result, these ads must be approved by CMS before use. CMS will also review previously submitted advertisements to ensure compliance with CMS requirements.

The Memo also notes that CMS will enhance its review of select marketing materials submitted under File & Use criteria, review selected marketing materials previously submitted under File & Use criteria, review all marketing complaints received during AEP, target oversight and review of MAOs and Part D sponsors with higher rates of complaints during the AEP, review recordings of agent and broker calls with potential enrollees and continue secret shopping.

Consequently, CMS recommended that MAOs and Part D sponsors implement the following requirements and best practices during the AEP:

- Ensure beneficiaries know how to file a marketing complaint with 1-800-MEDICARE or the plan, as well as highlight for beneficiaries that it is important to provide an agent or broker name, if possible. Plans must clearly display this information on plan websites and include this information in all mailings.
- Immediately review all allegations raised by any source against an agent or broker.
- Take all necessary and appropriate action to address inappropriate agent behavior.
- Track complaints against each agent or broker, looking for any outliers with respect to rapid disenrollments.
- Ensure agents and brokers obtain Scope of Appointment (SOA) forms. Plans should remind agents and brokers that they may *only* discuss with potential enrollees those products that have been agreed to in advance on the SOA. CMS retains the right to request copies of SOAs.

- Review "upstream" entities associated with agents who are outliers with respect to complaint numbers and determine potential patterns or connections to potentially inappropriate Field Marketing Organization activities.

- Ensure all agents and plan marketing materials clearly state when certain benefits may not be available to all enrollees. CMS may determine that the agent's activity or marketing is misleading if the benefits being marketed are only available to a subset of plan members.

- Ensure all agents and brokers review the required Pre-Enrollment Checklist with a beneficiary *prior* to enrollment. The items in this checklist must be covered in full and the agent must confirm that the beneficiary understands all items addressed.

- Provide translation services for beneficiaries with limited English proficiency. For those beneficiaries who have requested documents in a language other than English, the plan must continue to provide required documents in that language until the beneficiary has changed his or her request.

- Provide agents with a list of required questions or topics that they must cover in their sales presentations particularly basic topics or questions, such as use of provider specialists, whether the beneficiary is looking for a lower premiums and copays, may need DME, or whether the beneficiary has questions about the costs associated with the plan.[60]

In addition to the FAQs and Memo, Ron Wyden, the Chairman of the United States Senate Committee on Finance, sent a letter in August 2022 to 15 state insurance commissioners and state health insurance assistance programs requesting information about deceptive marketing practices being conducted by MA plans and Part D sponsors, agents and brokers, and others.[61] Wyden asked for information about the types of complaints that states are receiving regarding Medicare Advantage and Part D marketing, the responsibilities of agents and brokers to protect consumers from false or misleading marketing, and whether certain types of organizations account for disproportionate shares of complaints. He also asked whether there are certain benefits that are associated with more complaints, and whether enrollment in certain products results in a greater number of prescriptions being filled by a particular pharmacy or pharmacy chain.

In November 2022, the Committee released a report entitled "Deceptive Marketing Practices Flourish in Medicare Advantage" ("the Report").[62] The Report found that there was an increase in complaints concerning mail advertisements, television advertisements, telemarketers, and robo-calls related to Medicare plans. States also reported marketing of plans to beneficiaries with dementia, beneficiaries being enrolled in a new plan without their consent, and examples of beneficiaries being switched to plans that did not cover their providers--all of which led to substantial disenrollment. In addition, ten states reported instances of provider network confusion, where the beneficiary was switched into a new plan and was unaware that their current doctors were not covered under their new plan's network until they began to use the new plan. Similarly, the Report also highlighted a complaint where a beneficiary was not told that his new Part D plan did not cover his medications, which he realized only after he went to the pharmacy to fill his prescriptions.

Hours after the Report was released, the New York Times reported on the magnitude of the complaints within the Report, including complaints about companies selling Medicare plans while posing as the Internal Revenue Service and other government agencies.[63]

The Committee urged CMS and Congress to take the following actions:

1. Reinstate MA plan requirements loosened during the Trump Administration such as:
   - Conduct regular proactive oversight over a broad range of marketing materials to ensure that MA plans and their subcontractors are not purposefully misleading beneficiaries.
   - Prohibit educational events and marketing events from happening on the same day at the same place.
   - Require marketing materials to describe the grievance and appeals process.
   - Require plans to report unlicensed agents to the state and notify beneficiaries who were enrolled in a plan by an unlicensed agent.
2. Monitor MA disenrollment patterns and use enforcement authority to hold bad actors accountable.
3. Require agents and brokers to adhere to best practices.
4. Implement robust rules around MA marketing materials and close regulatory loopholes that allow cold-calling.
5. Support unbiased sources of information for beneficiaries, including State Health Insurance Assistance Programs and the Senior Medicare Patrol.

Soon after the Report was released, Senators Maggie Hassan, D-NH, and Roger Marshall, R-KS, introduced a new bipartisan bill ("the Bill") that would add new information to the Medicare & You handbook on health plan choices and supplemental insurance.[64] According to a press release issued by the senators, the *Medicare & You Handbook Improvement Act of 2022* would improve beneficiary education by requiring CMS to include information on the following:

- A description of what utilization management techniques are including prior authorization and step therapy, and how a beneficiary can find which techniques apply under a specific MA plan or prescription drug plan.
- A description of the network sizes of MA plans relative to the number of health care providers who accept Original Medicare.
- A description explaining that when seniors switch to an MA plan and later switch back to Original Medicare, they may be prohibited from purchasing supplemental coverage or else have to pay significantly higher premiums.[65]

When CMS finalized its new regulations and guidance on TPMOs, it indicated the possibility of issuing even more regulations and guidance to address abusive marketing practices.[66] The Report and the Bill likely signal that CMS is one step closer to issuing additional requirements for MAOs, Part D sponsors and third party marketing organizations related to the sale and marketing of MA and Part D plans.

OPDP Year in Review

By: Dominick DiSabatino and Alexandra Kitson

The Office of Prescription Drug Promotion (OPDP) in the Food and Drug Administration (FDA) issued only three untitled letters this year to pharmaceutical manufacturers for making false and misleading claims that caused a drug product to be misbranded, limiting enforcement to violations FDA felt were "concerning from a public health perspective,[67] including one for a product with a boxed warning[68]. In addition, OPDP issued one warning letter related to an unapproved drug product being promoted for COVID-19 treatment.[69] This marked a continuing downward trend in enforcement, following only six enforcement letters (i.e., both untitled and warning letters) issued by OPDP in each 2021 and 2020 and ten issued in 2019.

OPDP did not have to look far this year to find the subjects of their enforcement letters. All three untitled letters concerned materials that were submitted under Form 2253, which pharmaceutical manufacturers are required to use to submit all promotional materials at the time of first use. Two letters involved violations OPDP had already expressed concerns about in prior communications,[70] and one letter concerned a promotional communication that was specifically brought to FDA's attention through the Bad Ad Program[71], a program designed to help healthcare providers recognize and report potentially false or misleading prescription drug promotion.[72]

All three of the untitled letters issued by OPDP in 2022 addressed the familiar themes of false or misleading benefit and risk presentation.

- **Eli Lilly and Company.** OPDP issued an untitled letter dated January 19, 2022 to Lilly related to false and misleading claims made about its product, TRULICITY® (dulaglutide) injection in an Instagram post. OPDP found that the post failed to adequately communicate Trulicity's FDA-approved indication and the limitations of use, and failed to include material information from the warnings and precautions and minimized other risk information.[73]

- **Bausch Health Companies Inc.** OPDP issued an untitled letter dated March 31, 2022 to Bausch relating to a DTC video and a healthcare professional website for DUOBRII® (halobetasol proprionate and tazarotene) lotion, that minimized risks associated with the product, failed to include information related to serious risks associated with the product and made clinical superiority claims without support.[74]

- **Althera Pharmaceuticals, LLC.** OPDP issued an untitled letter dated June 2, 2022 to Althera Pharmaceuticals relating to promotional communication intended for healthcare providers detailing ROSZET® (rosuvastatin and ezetimibe), tablets for oral use, that made misleading claims about efficacy, omitted material information, and failed to present contradictions, warnings and precautions for the product with the same prominence and readability as the benefits.[75]

While OPDP's enforcement remained limited this year, it served as a reminder of the key guardrails pharmaceutical manufacturers need consider in their prescription drug promotion.

Material information matters. Promotional communications misbrand a drug if such communications are false or misleading with respect to risk. Even if some risk information is included, omitting or minimizing any material risk information can be considered false or misleading.

- In its letter regarding Roszet, OPDP determined claims about lowering LDL cholesterol were misleading because they omitted material information about the relative effect of diet. One of Roszet's indications in the PI is as an adjunct to diet, and the omission of this information misleadingly suggested that Roszet, alone, may provide the stated benefits for that specific indication.[76]

- In its Trulicity letter, OPDP found the video contained misleading claims because it prominently communicated that Trulicity could help "lower A1C along with diet and exercise," but it failed to adequately communicate Trulicity's FDA-approved indication and the limitations of use.[77]

Studies should support the claims you are making. Promotional materials may be violative if they make claims that are not supported by adequate evidence, including those that: (1) misrepresent the data from studies; (2) rely on cherry-picked data; or (3) incorrectly convey statistical significance.

- In its Roszet letter, OPDP found that efficacy claims were not sufficiently supported by a study as numbers used were not the findings of any study of Roszet, but appeared to have been retrospectively calculated by combining the results of two separate and unrelated studies - differing in patient population, type and dose of treatment, and duration. OPDP also expressed concerns about studies using modified intent-to-treat (mITT) and last observation carried forward (LOCF) methodologies and stated that, in general, those methodologies introduce bias and limit conclusions that can be drawn.[78]

Consistent with label claims require proper evidentiary support. Consistent with label messaging (i.e., the efficacy and mechanism of action section), may be considered false or misleading without appropriate context.

- The Duobrii website included claims of "demonstrated synergy" and "superior efficacy" of Duobrii versus the aggregated results of two monotherapies.[79] OPDP determined that the trial was not designed to support the efficacy conclusions as it was based on data derived from post hoc analyses of a single phase 2 trial, of limited sample size, which compared Duobrii separately to its individual components and vehicle.[80]

Disclaimers are not always enough. Promotional communications must be truthful and non-misleading. Disclaimers are often used to add additional context to claims made in promotional materials, but are not always enough to mitigate the misleading nature of the material.

- While the video did include a superscript indicating that "individual results may vary," and OPDP acknowledged that "these claims may be an accurate reflection of the spokesperson's own experience," OPDP noted that it was not enough to mitigate any misleading impressions of clinical superiority.[81]

Pay attention to prominence. Promotional material must present a "fair balance" of risk and benefit information. This requires risk information to be presented with the same prominence as benefit information, including with regards to font size and style, format, contrast, location and use of white or blank space.

- In its Roszet letter, OPDP found material to be misleading because the "most common adverse reactions were presented in the body of the piece in table format and under the header "Safety and Tolerability," while more serious risks were relegated to the bottom of the page and the subsequent page.[82]

- In its Trulicity letter, OPDP determined that risk information wasn't adequately presented as the post prominently presented benefit claims emphasized by colorful, compelling, and attention-grabbing fast-paced visuals with large-moving superimposed text, while the risk information is in a small window relegated to the bottom of the post and is presented using fast-paced, scrolling, small font that is difficult to read.[83]

Watch your visual representations. Promotional materials will misbrand a drug if they are false and misleading with respect to risk. In addition to narrated or textual statements, visual representations can also cause communications to be considered misleading if material risk information is not included.

- In the DUOBRII promotional material, a woman appearing to be of reproductive age with two young children states that she uses DUOBRII frequently and often in the case where she has a flare up of her psoriasis.[84] OPDP found this to be misleading as there was no recitation of the warning and precaution section of the PI advising pregnant females to obtain a pregnancy test within 2 weeks prior to initiation of DUOBRII therapy and to use effective contraception during treatment. In addition, a woman is shown outside, with shoulders and arms exposed, discussing how she needed to wear long sleeve shirts "even when it was warm" to hide her psoriasis and touting the success of her treatment. Without including the warnings and precautions from the PI about photosensitivity and the need for use of sunscreen and protective clothing, OPDP found this to be misleading.[85]

LOOK AHEAD TO 2023

With OPDP enforcement activity continuing to decline, we must look even more carefully at the letters that FDA chooses to issue. Looking at the enforcement in 2022, or lack thereof, one thing is clear - OPDP continues to focus on the most repeated and blatant violations that present the largest and most serious risks to public health. In its Roszet letter, OPDP went so far as to emphasize that, in addition to its serious risks, Roszet is indicated for the treatment of high cholesterol - "a significant public health concern that affects millions of adults in the United States."[86] In the coming year, we should expect that products with serious risks and those that have previously been the subject of OPDP communications to continue to be the most likely targets. But, the converse is also true—at least one violation pointed out by FDA related to a more nuanced issue in substantiation and contextualization. The Duobrii letter demonstrates OPDP's willingness to dive deeper and take a closer look at the evidentiary support for each claim. Pharmaceutical manufacturers should take the Duobrii letter as a warning to carefully evaluate both the references and the context provided in OPDP communications to ensure their consistent with label messaging is not misleading.

Where consumers go, pharmaceutical manufacturers will go; and where pharmaceutical manufacturers go, OPDP will eventually follow. Pharmaceutical manufacturers continue to utilize social media, such as Instagram, to reach consumers and healthcare professionals - and as we saw with the Trulicity letter, OPDP continues to pay close attention. With new platforms debuting constantly, and the lack of clear guidance from FDA, these mediums are ripe for risk. The time and space constraints of most of these social media platforms, along with the combined use of audio, video, text & graphics and influencers requires a complex risk evaluation and careful regulatory analysis.

Digital Health: Significant FDA Policy Developments in 2022

By: Allison Fulton, Justine Lei and Cortney Inman

In 2022, FDA retreated from a flexible approach to its regulation of digital health in two key areas: (1) its Pre-Certification Program for software as a medical device (SaMD) and (2) its guidance on Clinical Decision Support (CDS). In both cases, FDA's proposed flexible approach was tampered down — in the first case by a lack of authority to implement a more flexible model for premarket clearance of software changes and, in the second, by a desire to provide clarity to industry on how FDA plans to enforce requirements for CDS software.

I. FDA ENDS SOFTWARE PRE-CERTIFICATION PROGRAM

On September 26, 2022, the U.S. Food and Drug Administration (FDA) released its final report discussing the Agency's findings from the Software Precertification (Pre-Cert) Program. The release of this report marks the completion of the Pre-Cert Program and FDA's backing away from its vision of a streamlined software product review.

Pre-Cert Program – FDA's Vision

The Pre-Cert Program was launched as a pilot program at the end of 2017 with the intention of developing a streamlined premarket review process for software as a medical device (SaMD). Under the Pre-Cert Program, FDA would determine whether a company meets certain quality standards for software design, validation and maintenance and if so, "pre-certify" the company. Pre-certified companies would then be able to introduce software changes and iterations under tailored regulatory controls (and without necessarily submitting a new 510(k) notification). In some cases for low-risk devices, pre-certified companies would not be required to submit a premarket submission at all. FDA would rely on post-market data for assurance that the software device remains safe and effective during its product lifecycle and to support new uses of the device.

The program's intent was to leverage a company's demonstrated culture of quality and product post-market performance to replace the traditional 510(k) submission for certain product changes. The program's four essential components reflect the total lifecycle of the product: (1) Excellence Appraisal; (2) Review Determination; (3) Streamlined Review; and (4) Real-World Performance.

Throughout 2018, FDA solicited feedback from stakeholders, which continued into 2019. In early 2019, the Agency released the Working Model version 1.0[87], Test Plan[88], and Regulatory Framework[89], followed by a mid-year update[90] that disclosed learnings on the Excellence Approval component. In late 2020, the Agency released an update on the status of the Pre-Cert Program with key learnings and next steps pertaining to Excellence Appraisal, Streamlined Review, and collection of Real-World Performance data.[91]

Key Findings – An Unworkable Program

Ultimately, FDA found that the Agency could not implement the Pre-Cert Program under its current statutory authority. From its inception, the pilot Program materials noted that the current regulatory framework was not flexible enough to meet the pace of technological advancements in the medical device software industry.[92] Although FDA was not specific about how it lacks authority to implement the program, the program garnered criticism for its departure from statutory requirements for the premarket approval process, device classification, and post-market surveillance.

First, the streamlined approval process set forth in the Pre-Cert Program may not meet specific requirements for premarket notification and submissions under the Federal Food, Drug and Cosmetic Act (FDCA) and its implementing regulations. Second, FDA's oversight of devices has traditionally been front-loaded to premarket review with comparatively limited post-market surveillance. The Pre-Cert Program attempts to shift this paradigm to rely more heavily on real-world performance data in a post-market setting — at least for low-risk devices.

In executing the pilot, FDA also encountered numerous challenges, such as limitations on the types of devices available for consideration and an inability to require participants to submit information that was not already required under existing statute.[93] FDA found that the *de novo* submission-based approach outlined in the Test Plan was not optimal because it is limited to devices with no substantially equivalent predicate device. In addition to the limitation on devices available for consideration, FDA also was challenged by an inability to require participants to submit information that was not already required under existing statute.[94] Although pilot participants voluntarily submitted data and engaged with the program, FDA found that the results were difficult to harmonize into consistent, repeatable methodologies.[95]

Nonetheless, the Program did provide FDA with insights into how companies design, develop, and manage SaMD digital health products.[96] These insights helped FDA validate methods that could work for regulatory oversight and where further development is needed.[97] For example, one gap for further development included the creation of a clearer description of what elements should be evaluated during Excellence Appraisals.[98] FDA was able to evaluate and devise a list of nine Key Performance Indicators (KPIs) that could be used in the future to assess organizational excellence.[99]

What's Next for SaMD

Based on the Agency's findings, FDA still thinks that the best method for regulating SaMD is an organization-based approach.[100] FDA needs a more agile regulatory framework that would allow for flexibility to regulate SaMD under a framework that is geared toward continual improvement, and not static product design phases (i.e., the more traditional device development model). To do that, FDA needs congressional help.

Until then, FDA will continue to develop guidance documents and other policies under its current regulatory framework to improve efficiency of its regulatory oversight over SaMD.[101] This flexible approach could signal an intent to not actively enforce 510(k) submission requirements for low-risk software and changes to such software, or maybe a potential down-classification, or 510(k) exemption, for certain categories of low-risk software. Either way, companies with solid software quality excellence records, and robust post-market data on the safety and quality of iterative changes to the software, may see room for continued development of novel software without intense scrutiny from FDA.

II. FDA LIMITS ENFORCEMENT DISCRETION FOR CLINICAL DECISION SUPPORT SOFTWARE

On September 22, 2022, FDA issued its Final Guidance on Clinical Decisions Support Software.[102] The Final Guidance narrows FDA's interpretation of the exemption criteria for clinical decision support ("CDS") software resulting in the inclusion of software functions as "devices", which were previously exempted. In addition, FDA has also excluded from exemption software functions intended to support time-critical decision-making, and is now silent on its risk-based enforcement discretion policies for CDS functions that may meet the definition of "device".

CDS – Brief Overview

Clinical decision support (CDS) software is software that is intended to provide health care providers and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. Section 3060(a) of the 21st Century Cures Act (the Cures Act), which was signed into law in December 2016, amended the definition of "device" in the Federal Food, Drug, and Cosmetic Act (FDCA), to exclude certain software functions, including low-risk CDS. [103],[104]

Specifically, the FDCA now excludes from the definition of device CDS that meets all of the following four criteria:

(1) not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;

(2) intended for displaying, analyzing, or printing medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

(3) intended for supporting or providing recommendations to a health care professional (HCP) about prevention, diagnosis, or treatment of a disease or condition; and

(4) intended for enabling such HCP to independently review the basis for such recommendations (so that it is not the intent that such HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient).

Notably, CDS that is intended for patients is not exempt from regulation, nor is CDS that interprets or analyzes a medical signal (*e.g.*, ECG) or a medial image (*e.g.*, patient scan).

CDS Final Guidance – Limited Enforcement Discretion

While FDA final guidance documents typically do not depart in significant ways from draft guidance documents, FDA's final CDS guidance represents a step back from its prior enforcement discretion policy.[105] Interestingly, the Final Guidance: (1) eliminated an entire section of the draft guidance that contained numerous examples of CDS for which FDA would exercise enforcement discretion, and (2) removed the discussion of the International Medical Device Regulators Forum (IMDRF) framework for regulating software as a medical device (SaMD).

FDA previously released two draft versions of the CDS guidance, the first in 2017[106] and the second in 2019.[107] In the 2019 draft guidance, FDA provided many examples of software that met the definition of CDS, but for which FDA intends to exercise enforcement discretion. The examples in the 2019 draft guidance addressed commenters' requests for enforcement discretion over "low impact" CDS that were intended for patients (and hence, did not meet the fourth criterion). FDA also incorporated risk-based principles set forth in the IMDRF framework, which sought to promote international consensus on the regulation of SaMD.[108]

The Final Guidance eliminated entirely the examples of enforcement discretion and the discussion of the IMDRF framework. FDA did so in an attempt to provide clarity on what it considers to be regulated CDS. While the elimination of the IMDRF framework generally does resolve ambiguity, the elimination of the enforcement discretion examples prompts questions over whether FDA intends to exercise discretion over low-risk CDS intended for patients. The Final Guidance also introduces new considerations for the third criterion that effectively narrow categories of CDS that could be exempt. In particular, FDA introduced a new element of whether the CDS is intended to support a time-critical decision (*e.g.*, an emergent care scenario).

What's Next for CDS

We think the Agency will continue to strike a balance between permitting innovations in CDS, among other digital health products, to flourish and asserting its enforcement authority. The Agency has made strides in the past few years to learn from industry, and it will continue to look for opportunities to partner with industry to shape policy moving forward. Although the Final Guidance may limit FDA's view of exempt CDS, we think that FDA will likely continue its hands-off approach to low-risk CDS, even if the CDS is patient-focused. FDA will continue to actively regulate medium-risk and high-risk CDS, especially those that interprets medical images (*e.g.*, CT scans) and those that lack transparency in their underlying algorithms.

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2023 Top-of-Mind Issues for Life Sciences Companies

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