Something Old, Something New: Hot Topics and Enforcement Trends of 2023

December 27, 2023

By: Alicia Whittlesey

As 2023 ends and we start a new year, there are several notable hot topics and enforcement trends related to the pharmaceutical, medical device, and biotech industries that have captured our attention and we are keeping an eye on in 2024. While some of these developments may not be surprising, if viewed from a different perspective or when additional context is provided, some may provide that "aha" moment prompting you to want access to more information.

- **Joint collaboration among DOJ, HHS/OIG, and FTC**: Additional measures are being taken by DOJ, HHS/OIG and FTC to provide oversight, coordination, training, and enforcement regarding different areas such as unfair competition, protection of consumers, and deceptive trade practices: (e.g. misrepresentations, misleading advertising, non-compliance with privacy policies, etc.). These agencies are sharing data and information and at times appear to be joining forces.

- **Compliance Program Plans and Initiatives to Prevent Healthcare Fraud and Abuse**: HHS/OIG has issued a newly updated, user-friendly General Compliance Program Guidance (GCPG). The GCPG encourages voluntary self-disclosure, and focuses more on the role, infrastructure (which still includes the seven key elements), implementation and execution, assessment, and enforcement of an effective and efficient Compliance Program. This is another area where there appears to be more of a joint effort among the different enforcement agencies.

- **State and Federal Privacy Laws**: It is certain that the importance of protecting personal health information including how such data is collected, stored, shared, and used from both a state and federal perspective is not going away. Within the past year alone, we have seen several states pass privacy legislation that regulates the collection, use, and sharing of consumer information. In fact, there is anticipation that there will be even more comprehensive state privacy laws related to consumers and the collection of personal information/data to come. Other areas of focus include those laws and regulations related to CAN-SPAM, TCPA, and other considerations from an opt-in/consent and notice perspective.

- **Artificial Intelligence (AI) and Information Security**: With the rapid advancements in AI technologies such as ChatGPT, new legal challenges have emerged related to intellectual property, data protection, regulatory compliance, and ethical considerations. While the use of AI in the life sciences industry, such as in clinical trial recruitment, wearable medical devices, and drug discovery, has the potential to advance scientific research and improve patient care, the lack of data protection/privacy measures or clear guidance or oversight, along with the possibility of misinformation and ethical concerns, pose tangible risks to the industry. This is another area to watch as it promises to garner attention from regulatory agencies. Additionally, with the EU on the brink of passing comprehensive AI legislation, the US is likely to follow.

- **Direct-to-Consumer Advertisements/Promotion**: The FDA has continuously shined a spotlight on promotional drug advertisements, and enforcement in this area is increasing as other agencies, including the FTC, are directing their attention to help protect the healthcare community. For example, the FTC has provided a final rule and other guidance related to the presentation of efficacy and risk information, including requiring a major statement in television or radio drug advertisements that provides side effects and contraindications in a "clear, conspicuous, and neutral manner."

- **State Price Transparency/Disclosure Laws**: Many states require price disclosures and sales representative registration requirements when "promoting" or "marketing" to a prescriber. Connecticut is one of the most recent states that passed a law requiring such disclosures and registrations with more to come. Awareness of these specific requirements is important so that companies can continue to promote their products and allow sales representatives access to customers.

- **Provision of Scientific Information to Healthcare Professionals on Unapproved Uses of Approved Products**: The concept of "scientific exchange" is not new however, the FDA has provided additional draft guidance in its "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers." The goal of this guidance appears to clarify recommendations for a company to consider when communicating and/or presenting scientific information to HCPs for an unapproved use, along with describing certain elements to support the information conveyed.

- **Use of Endorsements, Testimonials, and Influencers/Endorsers in Advertising**: Social media has always been a hot topic with the FDA in terms of the regulatory requirements for promotional labeling. Now, additional attention in areas such as the use of "endorsements" has also been emphasized by the FTC, with its revisions to the "Guides Concerning the Use of Endorsements and Testimonials in Advertising." Not only do these "Guides" provide clarifying definitions but also furnish examples of situations that may require a disclosure where there appears to be an endorsement to a consumer.

- **Clinical Trial Activities**: Another area where there seems to be continued, combined interest by different enforcement agencies, including the FDA and DOJ to assist with consumer protection efforts, involves clinical trial activities. Such areas of interest include potential clinical trial fraud or research misconduct, HCP conflicts of interest in clinical trial activities, the integrity of clinical trial data and how it is used, research subject payments and reimbursement, and the informed consent process. For example, the FDA has finalized its "Guidance for IRBs, Clinical Investigators and Sponsors on Informed Consent" which provides requirements and elements of the informed consent process. The DOJ has also emphasized its priorities in this area at industry conferences and in other public forums.

- **Americans with Disabilities Act (ADA) and Web Accessibility**: The DOJ has prioritized the need for certain businesses, including the need for certain businesses that are open to the public, to confirm their websites are accessible to people with disabilities under ADA requirements. Indeed, it has published a guidance entitled, "Guidance on Web Accessibility and the ADA" on this very topic. Although the pharmaceutical industry has not been specifically identified in this guidance, many companies are proactively implementing actions to conform to such requirements.

Although the hot topics and enforcement trends described above are not exhaustive, we hope this will provide a snapshot into some of the significant areas of government concern and focus that may have an impact on your company and its operations with respect to your legal, regulatory, and compliance obligations. As you begin to gear up for another year with the development of new business strategies or a possible refresh or assessment of a company's current compliance program, keep these areas top of mind. Want to know more? Stay tuned for more information and services provided by Porzio's team of Life Sciences attorneys on these and other industry-related updates.