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GC Agenda

A round-up of major horizon issues for General Counsel

JUNE/JULY 2019

ANTITRUST

PHARMACEUTICAL PAY-FOR-DELAY AGREEMENTS

A recent FTC decision warns that the FTC is continuing its robust enforcement program addressing pharmaceutical companies' efforts to prevent or delay generic competition.

In *In the Matter of Impax Laboratories, Inc.*, the FTC found that Impax Laboratories LLC entered into an illegal pay-for-delay agreement with Endo Pharmaceuticals Inc. A pay-for-delay agreement (also known as a reverse payment settlement) involves a payment from a branded drug manufacturer to a generic drug manufacturer to settle patent infringement claims and delay the generic drug's market entry. The *Impax* decision is the first FTC decision that fully applies the US Supreme Court's rule-of-reason test for pay-for-delay agreements under *FTC v. Actavis, Inc.*

The FTC also recently:

- Reached separate settlements with Teva Pharmaceutical Industries Ltd. and Actavis relating to pay-for-delay agreements that restricted the market entry of generic drugs.
- Charged Surescripts, LLC with violating the antitrust laws to maintain its monopolies over the routing and eligibility markets for electronic prescription services.



Search [FTC Holds that Impax Entered into Illegal Pay-for-Delay Agreement](#) for more on this decision.

ICN FRAMEWORK ON COMPETITION AGENCY PROCEDURES

Global companies should take note that the Steering Group of the International Competition Network (ICN) recently approved the Framework on Competition Agency Procedures, a multilateral framework of procedures among global antitrust enforcement agencies to promote fundamental due process in antitrust investigation and enforcement.

The Framework sets out standards for participation, a cooperation process among participants, and a review process for those participants' antitrust investigation and enforcement procedures. The Framework also establishes fair and effective procedures for global antitrust enforcement, as well as standards for:

- Transparency and predictability, including that each participant make its antitrust laws relating to investigations publicly available.
- The investigative process, including that any person or entity under investigation be notified and given the legal basis for, and information regarding the conduct at issue in, the investigation.
- Certain processes and procedures, including the timing of investigations and enforcement proceedings, confidentiality, conflicts of interest, notice and an opportunity to defend, representation by counsel and privilege, decisions in writing, and independent review.

The FTC registered for the Framework on May 1, 2019.

CAPITAL MARKETS & CORPORATE GOVERNANCE

GUIDANCE ON MATERIALITY DETERMINATIONS

The SEC's recent agreement to amend Elon Musk's settlement agreement to define when communications, including through Twitter, are sufficiently material that they must be pre-approved by securities counsel, provides helpful guidance to reporting companies.

The SEC specifically noted that pre-approval would be required for communications about:

- The company's financial condition, statements, or results, including earnings or guidance.
- Numbers that either have not been previously published in official company guidance or deviate from previously published official company guidance, including:
 - production numbers or sales or delivery numbers (whether actual, forecasted, or projected); or
 - projection, forecast, or estimate numbers regarding the company's business.
- Potential or proposed mergers, acquisitions, dispositions, tender offers, or joint ventures.
- New or proposed business lines.
- Events regarding the company's securities, credit facilities, or financing or lending arrangements.
- Non-public legal or regulatory findings or decisions.
- Any event requiring the filing of a Form 8-K by the company, including:
 - a change in control; or
 - a change in the company's directors or officers.
- Other topics that the company or the majority of the independent members of its board may request that would protect the interests of the company's shareholders.

Reporting companies should review their Regulation FD and insider trading policies and consider conforming their examples of material information to this list. However, while this list may offer guidance for other reporting companies considering their own disclosure obligations, these companies should also keep in mind that this list is the result of a heavily negotiated settlement.

 Search [Corporate Governance Case Study: Tesla, Twitter, and the Good Weed](#) for more on the SEC's enforcement action against Musk.

COMMERCIAL TRANSACTIONS

FDA REGULATION OF CANNABIS PRODUCTS

Companies interested in the emerging cannabis industry should be aware that the FDA is evaluating regulatory pathways for cannabis-containing and cannabis-derived products, according to a recent statement by then-FDA Commissioner Scott Gottlieb.

The focus on these products has intensified since the Agriculture Improvement Act of 2018 established a new

category of cannabis and cannabis derivatives with extremely low concentrations of tetrahydrocannabinol (THC) classified as "hemp," and removed hemp from the Controlled Substances Act. However, this did not change the FDA's authority to regulate cannabis-containing and cannabis-derived products under the federal Food, Drug, and Cosmetic Act (FDCA).

In particular, the FDA is taking steps to advance a legal marketing framework for cannabis-containing and cannabis-derived products, such as:

- Holding a public hearing, and seeking public comment (until July 2, 2019), about the regulatory oversight necessary for cannabis-containing and cannabis-derived products.
- Forming an internal agency working group to explore legally marketing dietary supplements and conventional foods containing cannabidiol (CBD), including any necessary statutory and regulatory changes, as well as the public health impact of this marketing.
- Answering frequently asked questions about cannabis-containing and cannabis-derived products.
- Issuing warning letters to companies that illegally market CBD products (such as the warning letters the FDA and the FTC sent to three companies in March 2019 for marketing CBD as a dietary supplement that would treat and cure several serious health conditions).

Companies should note that while the FDA is taking steps to establish a regulatory framework, introducing food and beverages containing CBD or THC into interstate commerce, or marketing CBD- or THC-infused products as dietary supplements, remains illegal under the FDCA, and the FDA will continue to hold companies accountable for illegally marketing these products.



Search [Counseling a Cannabis-Related Business Overview](#) for more on the regulation of cannabis.

EMPLOYEE BENEFITS & EXECUTIVE COMPENSATION

RETIREMENT PLAN ERRORS

The IRS recently issued Revenue Procedure 2019-19, which expands the availability of the Self-Correction Program (SCP) under the Employee Plans Compliance Resolution System (EPCRS) for retirement plans, and permits retirement plan sponsors to self-correct more errors without preparing submissions and paying user fees to the IRS.

Self-correction is available for certain common participant loan errors in 401(k) plans, including:

- Loans that are defaulted for failure to repay within the loan term.
- An excessive number of loans under the plan document.

For the first time, self-correction is also available for certain plan document failures, such as the failure to adopt a required amendment. Operational failures can be self-corrected using a retroactive plan amendment, if certain requirements are met.

Previously, these errors could only be corrected by preparing a submission and paying a user fee to the IRS under the Voluntary Correction Program (VCP). VCP user fees range from \$1,500 to \$3,500, depending on plan assets.

The SCP expansion is expected to:

- Be especially helpful for participant loans, a frequent source of errors in 401(k) plans.
- Reduce the number of VCP submissions that plan sponsors must make, saving time and expense.

Plan sponsors should monitor the ability to use self-correction for any errors that arise. Even with the recent changes, not all loan failures can be self-corrected, and plan sponsors should ensure that any error and self-correction meet the eligibility requirements under EPCRS.



Search [IRS Updates EPCRS and Expands Self-Correction Program in Rev. Proc. 2019-19](#) for more on self-correction of retirement plan errors.

FINANCE

SUSTAINABILITY-LINKED LOAN PRINCIPLES

The Loan Syndications and Trading Association, together with the Loan Market Association, the Asia Pacific Loan Market Association, and representatives from leading financial institutions, recently published Sustainability Linked Loan Principles (SLLP), which identify and assist loan parties in understanding the key characteristics of sustainability-linked loans.

Sustainability-linked loans enable lenders to incentivize improvements in a borrower's sustainability profile by aligning the terms of the loan (for example, pricing) to the borrower's performance against sustainability performance targets (for example, improved energy-efficiency ratings of buildings or reduced greenhouse gas emissions in manufactured products).

The SLLP focus on a borrower's:

- Overall corporate social responsibility strategy.
- Sustainability profile.
- Progress and verifiable performance measured against sustainability performance targets.

The SLLP, together with the previously published Green Loan Principles (GLP), aim to create widely accepted principles for sustainable and green loan products. The SLLP, like the GLP, are voluntary guidelines that market participants may apply on a deal-by-deal basis.



Search [Sustainability-Linked Loan Principles](#) for more on the SLLP.

DIGITAL ASSETS

The SEC Strategic Hub for Innovation and Financial Technology recently published a framework for analyzing whether a digital

asset is offered and sold as an investment contract, and is, therefore, a security subject to the federal securities laws.

The framework is an analytical tool to assist market participants in assessing whether the federal securities laws apply to the offer, sale, or resale of a digital asset. Specifically, the framework is geared to market participants that conduct the following activities related to digital assets:

- Offering, selling, or distributing.
- Marketing or promoting.
- Buying, selling, or trading.
- Facilitating exchanges.
- Holding or storing.
- Offering financial services, such as management or advice, or other professional services.

The framework follows the *Howey* test for determining the existence of an investment contract. Under *Howey*, an investment contract exists when there is an investment of money in a common enterprise with a reasonable expectation of profits to be delivered from the efforts of others. The framework focuses on the third prong of the *Howey* test, the reasonable expectation of profits. The following factors are particularly relevant:

- Whether a purchaser is relying on the efforts of others.
- Whether certain characteristics are present to determine that there was a reasonable expectation of profit, such as whether the digital asset gives the holder rights to realize gain from capital appreciation.
- Whether other relevant considerations exist, such as whether the distributed ledger network and digital asset are fully developed and operational.

Market participants should recognize that the framework is not an SEC rule, regulation, or statement, and the SEC has neither approved nor disapproved its content.



Search [SEC Publishes Framework for "Investment Contract" Analysis of Digital Assets](#) for more on digital assets.

INTELLECTUAL PROPERTY & TECHNOLOGY

VOLITIONAL CONDUCT

Website operators that allow users to post content should evaluate the risk of direct copyright infringement liability in light of a recent Second Circuit decision.

In *BWP Media USA Inc. v. Polyvore, Inc.*, the Second Circuit found that genuine disputes of material fact precluded summary judgment on whether the photo-sharing website Polyvore:

- Directly infringed BWP's copyrights by automatically creating and displaying multiple resized images of BWP's photos originally uploaded by users.
- Qualified for the Digital Millennium Copyright Act (DMCA) Section 512(c) safe harbor for website operators that store copyrighted material "at the direction of a user" when a

user's uploading of a single copyrighted image triggered the automatic production and display of additional, altered copies.

The Second Circuit reaffirmed that direct infringement claims involving website operators and other automated service providers require a showing of volitional conduct. This holding joins the Second Circuit with the Ninth and Fifth Circuits in:

- Rejecting the argument that the US Supreme Court had implicitly rejected a volitional conduct requirement in *American Broadcasting Companies, Inc. v. Aereo, Inc.*
- Limiting the *Aereo* decision to the discrete area of television rebroadcasting.

However, the three separate concurring opinions issued by the *Polyvore* panel show that the framework of the fact-intensive volitional conduct analysis, as well as the contours of the DMCA safe harbor, are still taking shape. Given the increased legal uncertainty for website operators, counsel should examine:

- Whether any reproduction and display of third-party copyrighted material, even if performed automatically, exceed the scope of a user's request or direction.
- The extent to which reformatting or other functions are performed on user-uploaded material.

 Search [Volitional Conduct Required for ISP Liability for Direct Copyright Infringement: Second Circuit](#) for more on this decision.

LABOR & EMPLOYMENT

BAN-THE-BOX LAWS

Employers should ensure that their recruitment practices comply with new and existing state and local ban-the-box laws, which restrict inquiries about an applicant's criminal history.

More than a dozen states and many localities have enacted ban-the-box laws, also known as fair chance laws. New Mexico became the latest state to enact a ban-the-box law in April 2019. These laws vary in detail, but all prohibit employers from asking about criminal history on an employment application. Employers that intend to ask about an individual's criminal history must determine when the applicable state or local ban-the-box law permits this inquiry.

Compliance can be challenging for multistate employers. State and local laws vary regarding the timing of when employers may seek criminal history information, such as after the applicant's initial screening, interview, or conditional offer of employment. Multistate employers should:

- Evaluate the practical burden of implementing separate recruitment practices that comply with each applicable jurisdiction's individual requirements.
- Consider adopting a one-size-fits-all approach that complies with the requirements of the most restrictive law across all jurisdictions. For example, an employer may choose to wait until after a conditional offer of employment to ask about criminal history, request completion of a background check consent form, and conduct the background check.

Employers must also ensure that their recruitment practices comply with:

- The federal Fair Credit Reporting Act, when using third-party providers to conduct permissible background checks.
- Federal and state anti-discrimination laws, which restrict automatic criminal conduct exclusions and require analysis of different factors (for example, how much time has passed since the conviction).

 Search [Ban-the-Box State and Local Laws Chart: Overview](#) for more on state and local ban-the-box laws.

CLASS ARBITRATION

Employers seeking to avoid class arbitration should ensure their arbitration agreements are clearly drafted in light of a recent US Supreme Court decision on the availability of class arbitration.

In *Lamps Plus, Inc. v. Varela*, the Supreme Court held that when an arbitration agreement is ambiguous on the availability of class arbitration, courts may not compel arbitration on a classwide basis. The Supreme Court emphasized that arbitration is a matter of consent under the Federal Arbitration Act (FAA) and ruled that state law contract principles (for example, that ambiguity in a contract should be construed against the drafter) cannot substitute for the parties' express consent.

This decision provides relief for employers that seek to avoid class arbitration, but use arbitration agreements that lack the unambiguous class action waivers endorsed by the Supreme Court in *Epic Systems Corp. v. Lewis*. Nevertheless, employers should attempt to avoid drafting ambiguities that may lead to disputes regarding the parties' intent, particularly if the arbitration agreement is susceptible to more than one interpretation regarding the availability of class arbitration. In addition, employers drafting or reviewing their arbitration agreements should:

- Weigh the potential disadvantages of arbitration against the principal advantages noted by the Supreme Court.
- Clarify that the FAA governs the arbitration agreement.
- Specify:
 - the issues subject to arbitration;
 - applicable rules;
 - designated arbitrators; and
 - the parties' intent to arbitrate on an individual basis only.
- Be as clear as possible regarding the parties' intent.

For employers that are either undecided about the value of arbitration or concerned about the continuing validity of arbitration agreements, this decision reinforces the legitimacy and benefits of individual arbitration, such as efficiency and informality.

 Search [Supreme Court Limits Some Class Arbitrations](#) for more on this decision.

LITIGATION & ADR

FAIR DEBT COLLECTION PRACTICES ACT

The US Supreme Court has clarified Fair Debt Collection Practices Act (FDCPA) liability for businesses that enforce security interests by nonjudicial foreclosure.

In *Obduskey v. McCarthy & Holthus LLP*, a foreclosing law firm allegedly failed to verify a debt and stop foreclosure proceedings when a homeowner disputed a debt under the FDCPA. Certain interpretations of the FDCPA's primary definition of debt collector could have subjected the foreclosing law firm to broad liability. However, the Supreme Court ruled that the FDCPA excludes businesses that have the principal purpose of enforcing security interests, such as the foreclosing law firm, from that definition. The Supreme Court held that businesses that enforce security interests by nonjudicial foreclosure generally face FDCPA liability only for taking (or threatening to take) nonjudicial action to dispossess or disable property if either:

- There is no present right or intention to take possession of the property.
- The property is exempt by law from dispossession or disablement.

The Supreme Court, however, considered only conduct required by state law on nonjudicial foreclosure, not other conduct related to, but not required for, enforcing a security interest that might cause a security interest enforcer to fall within the primary definition of debt collector.

Given this decision, businesses that enforce security interests that strictly comply with the nonjudicial foreclosure steps required by state law and take no further steps can act with greater certainty to limit their FDCPA liability.

 Search [FDCPA Litigation: Key Issues and Considerations](#) for more on prohibited acts and liability under the FDCPA.

CONFIRMATION OF PARTIAL FINAL ARBITRATION AWARDS

A recent district court decision demonstrates that counsel should choose carefully when designating venue in arbitration clauses, especially where the parties may bring counterclaims against each other.

In *Standard Security Life Insurance Co. of New York v. FCE Benefit Administrators, Inc.*, the Northern District of Illinois held that, under Seventh Circuit precedent, it did not have jurisdiction to confirm a partial final arbitration award because the award did not determine all issues submitted to the arbitrators. In the underlying arbitration, the panel rendered a partial final award, which fully resolved the plaintiffs' claims, including damages, but left resolution of the defendant's counterclaim for a subsequent phase of the arbitration. Because the arbitration was not completed, the court held that the award was not final and, therefore, the court did not have jurisdiction to confirm it.

The district court's decision highlights a circuit split on the issue of confirmation of partial final arbitration awards. To facilitate

the quick enforcement of arbitration awards, counsel should therefore consider including a venue provision in the arbitration clause that designates a court in a federal circuit, such as the Second or Sixth Circuit, that allows confirmation of partial final arbitration awards that resolve an independent claim, even if other claims remain pending in the arbitration.

 Search [Enforcing Arbitration Awards in the US](#) for more on the enforcement of arbitration awards, including procedural issues and the grounds for enforcement challenges.

REAL ESTATE

LIBOR PHASEOUT

Parties to variable interest commercial real estate loan transactions should address the phasing out of the London Interbank Offered Rate (LIBOR) when drafting and negotiating loan documents.

Reference rates serve to benchmark variable interest commercial real estate loans against a mutually agreed standard rate. Until 2010, LIBOR was the most widely used reference rate. However, concerns about LIBOR's reliability and accuracy resulted in reforms and an announcement that LIBOR would be discontinued as of 2021.

The Alternative Reference Rates Committee (ARRC), whose members include JPMorgan Chase & Co., The Goldman Sachs Group, Inc., and Fannie Mae, has worked to find a replacement for LIBOR. ARRC has recommended an alternative, the Secured Overnight Financing Rate (SOFR), but SOFR has faced recent volatility.

Parties to variable interest commercial real estate loans can address the challenge of drafting and negotiating loan documents that will be in effect after 2021 with several approaches, including:

- Continuing to use standard forms that include LIBOR (with the assumption that loan documents will be construed to use LIBOR's replacement).
- Adding language stating that if LIBOR is inadequate or discontinued, the parties will mutually agree on an alternative.
- Adding a LIBOR successor rate definition that describes the successor rate if LIBOR is inadequate or discontinued.

Parties to these types of loans should be cognizant of these approaches and negotiate for the most favorable alternative.

 Search [Current Trends in LIBOR Successor Rate Provisions](#) for more on LIBOR successor rate language in recently filed credit agreements.

TAX

QUALIFIED OPPORTUNITY FUNDS

The IRS and Treasury Department recently released a second set of proposed regulations offering guidance to investors and fund

sponsors on the tax benefits available to investors who invest capital gains in qualified opportunity funds (QOFs).

A QOF is a partnership or corporation that invests directly or indirectly in low-income communities designated as qualified opportunity zones (QOZs) and holds at least 90% of its assets in qualified QOZ business property, or in partnerships or corporations that operate qualified QOZ businesses (QOZ entities). The tax benefits for an investor who invests pre-2027 capital gain in a QOF within 180 days of the gain recognition include:

- Gain deferral until December 31, 2026 (or if earlier, the date the QOF investment is sold or exchanged).
- Possible permanent exclusion of up to 15% of the gain.
- Permanent exclusion of gain from the post-acquisition appreciation of a QOF interest if an investor sells a QOF interest held for at least ten years.

The first set of proposed regulations addressed threshold questions on the QOZ regime, including which taxpayers can benefit from gain deferral and the types of gain eligible for deferral. The second set of proposed regulations provides additional guidance, including:

- Offering relief from the 90% asset test for cash contributed to a QOF within six months of an asset testing date.

- Allowing QOFs a 12-month grace period to reinvest proceeds from the disposition of QOZ property.
- Extending the ten-year gain exclusion to certain sales of property by a pass-through QOF (partnership, S-corporation, or REIT) for those QOF investors meeting the ten-year holding period requirement. However, taxpayers cannot rely on this rule until it is finalized and it is unclear how the rule applies if the QOZ business is held in a QOZ entity.
- Allowing property leased after December 31, 2017 to be treated as qualified QOZ business property if certain requirements are met (for both QOFs and QOZ entities).
- Treating unimproved land and previously used buildings vacant for at least five years as qualified QOZ business property if certain requirements are met (for both QOFs and QOZ entities).
- Identifying events that trigger inclusion of deferred gain.
- Allowing investors in certain cases to receive tax-free refinancing distributions from a partnership QOF without triggering deferred gain.
- Clarifying that profits interests are not eligible for QOZ tax benefits.

Except as noted above, investors and fund sponsors can generally rely on the proposed regulations before they are finalized if they apply the rules consistently.

GC Agenda Interviewees

GC Agenda is based on interviews with Advisory Board members and leading experts from Law Department Panel Firms. Practical Law would like to thank the following experts for participating in interviews for this month's issue:

ANTITRUST

Logan Breed
Hogan Lovells US LLP

Lee Van Voorhis
Jenner & Block LLP

Laura Wilkinson

CAPITAL MARKETS & CORPORATE GOVERNANCE

Adam Fleisher
Cleary Gottlieb Steen & Hamilton LLP

Karen Hsu Kelley
Simpson Thacher & Bartlett LLP

Robert Downes
Sullivan & Cromwell LLP

Jean Weng
Voya Financial, Inc.

EMPLOYEE BENEFITS & EXECUTIVE COMPENSATION

Elizabeth Dold
Groom Law Group, Chartered

Christina Cerasale
Seyfarth Shaw LLP

Jeffrey Lieberman
Skadden, Arps, Slate, Meagher & Flom LLP

Sarah Downie
Weil, Gotshal & Manges LLP

INTELLECTUAL PROPERTY & TECHNOLOGY

Jeffrey Cunard
Debevoise & Plimpton LLP

Richard Raysman
Holland & Knight LLP

LABOR & EMPLOYMENT

Michael Leggieri and Robin Samuel
Baker McKenzie LLP

Stephen Woods
Ogletree Deakins

Thomas Wilson
Vinson & Elkins LLP

LITIGATION & ADR

Timothy Splane
Timios, Inc.

REAL ESTATE

Kathleen Tarbox Muñoz
Hunton Andrews Kurth LLP

Andy Van Noord
Jones Day

Carrie Winkler
Vinson & Elkins LLP

TAX

Kim Blanchard
Weil, Gotshal & Manges LLP