Article Title: President Trump's Second Administration: Trade Policy Priorities and Legal Mechanisms Available for Their Implementation

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Date: 1/20/2025

Link: https://www.bipc.com/president-trump%E2%80%99s-second-administration-trade-policy-priorities-and-legal-mechanisms-available-for-their-implementation?utm_source=advisory&utm_medium=email&utm_campaign=2024-01-17_International_Trade

Summary: As President Donald Trump prepares to begin his second term today, the implications of his proposed tariffs have sparked debate.

Important questions remain as to how the incoming Administration plans to enact these tariffs.

Learn more about the several legal authorities that President Trump may rely on to impose tariffs or duties on all goods from specific countries, such as China and Mexico, or all goods imported into the United States from all foreign countries.

Industries: Government Relations & Public Policy, International Trade & National Security

Article: As President Donald Trump prepares to begin his second term today, the implications of his proposed tariffs have sparked debate. Depending on whom you ask, these tariffs and trade remedies may negatively impact the economy of the United States OR protect domestic production, American workers, and decrease the Federal deficit. Important questions remain as to how the incoming Administration plans to enact these tariffs.

President Trump campaigned on imposing universal tariffs and continues to support them, including tariffs of 10 percent on all Chinese goods in addition to any existing tariffs, a 25 percent additional tariff on goods from Mexico and Canada, and 20 percent on all imports from other countries.1 The aims of imposing universal tariffs are both economic and part of a larger foreign policy that is being pursued by President Trump.

Much of the reporting on President Trump's intended use of tariffs does not explain the legal authorities according to which tariffs or duties can be imposed. Article 1, Section 8 of the U.S. Constitution provides that Congress has the "power to lay and collect taxes, duties, imposts and excises . . ." President Trump could achieve success in implementing tariffs and/or duties through legislation due to the Republican majority in both houses of the incoming Congress. It appears more likely, however, that the President will seek to exercise executive power delegated to the President by Congress.

This advisory provides a primer on several legal authorities that President Trump may rely on to impose tariffs or duties on all goods from specific countries, such as China and Mexico, or all goods imported into the United States from all foreign countries (hereinafter "universal tariffs"). In this regard, President Trump is likely to use (at least in part) the International Emergency Economic Powers Act to justify the imposition of blanket tariffs. To impose tariffs on imports, President Trump may also rely on Section 122 of the Trade Act of 19742 or Section 338 of the Tariff Act of 1930.3 This article first reviews the three legal authorities that President Trump may use to impose either universal tariffs or blanket tariffs on certain countries such as Mexico and Canada.

In his second administration, President Trump will likely again make use of trade laws, including Section 301 of the Trade Act of 1974 and Section 232 of the Trade Expansion Act of 1962. In addition, Petitioners from the U.S. domestic industry are likely to continue to request initiation of antidumping and countervailing duty investigations in record numbers. This article provides background information on Section 301 and Section 232 investigations as well as information on how the domestic industry may seek the imposition of duties through filing antidumping and countervailing duty petitions with the U.S. International Trade Commission (the Commission) and the U.S. Department of Commerce (Commerce).

In addition, domestic industries themselves may request the initiation of many trade remedies discussed below, including investigations under Section 338 of the Tariff Act of 1930 as it appears that the domestic industry may petition the Commission to initiate an investigation,4 Section 301 of the Trade Act of 1974 under which the domestic industry may file a petition with the U.S. Trade Representative,5 Section 232 of the Trade Expansion Act of 1962 under which the domestic industry may file a petition with Commerce,6 and antidumping and countervailing duty investigations in which the domestic industry can file petitions before Commerce and the Commission.

International Emergency Economic Powers Act of 19777

The International Emergency Economic Powers Act (IEEPA) provides that "[a]ny authority granted to the President under Section 1702 of this title may be exercised to deal with any unusual and extraordinary threat, which has its source in whole or substantial part outside the United States, to the national security, foreign policy or economy of the United States, if the President declares a national emergency with respect to such threat."8 Notably, no President has ever imposed tariffs through using IEEPA as his legal authority, yet many argue that a President's authority under IEEPA is broad enough to do so.9 President Trump came close to imposing a tariff on all goods imported from Mexico under IEEPA in his first term to address "the emergency at the Southern border."10 Ultimately, an agreement with Mexico was reached prior to any tariffs under IEEPA taking effect.11 Given the continuing concerns with U.S. border security, it appears that President Trump may again seek to impose across-the-board tariffs on imports entering the United States from one or more countries, including possibly Canada and Mexico, or on imports from all countries through a universal tariff using IEEPA as a legal basis.

Section 122 of the Trade Act of 197412

Another law that has not been used in the past to impose duties and could be invoked by President Trump to address "large and serious United States balance-of-payments deficits" is Section 122 of the Trade Act of 1974.13 Section 122 allows the President, through presidential proclamation, to impose a temporary import surcharge not to exceed 15 percent ad valorem in the form of duties, in addition to those already imposed, on articles imported into the United States for a period not to exceed 150 days unless such period is extended by an Act of Congress.14 President Trump could rely on Section 122, conceivably upon his entry into office, to impose such duties pending other more permanent executive action. As previously noted, these duties could be extended through an Act of Congress or could be extended through federal legislation to make them longer lasting.15

Section 338 of the Tariff Act of 193016

Section 338 of the Tariff Act of 1930 is another legal basis under which President Trump could draw authority to impose duties. Notably, there is no precedent for the use of Section 338 in this manner, and President Trump's administration may, therefore, prefer to act under other more broad legal authorities.

According to Section 338, the President may declare, via proclamation, new or additional duties of up to 50 percent ad valorem or its equivalent on imports from foreign countries when he finds that the public interest is served and that the foreign country imposes, "directly or indirectly, upon the disposition in or transportation in transit through or re-exportation from such country of any article wholly or in part the growth or product of the United States any unreasonable charge, exaction, regulation, or limitation which is not equally enforced upon the like articles of every foreign country," and the President may also impose duties on imports from a foreign country that "[d]iscriminates in fact against the commerce of the United States, directly or indirectly,"

through a variety of possible methods that include by law or by administrative regulation or through any customs or port duty “in such manner as to place the United States at a disadvantage compared with the commerce of any foreign country.”17

In addition, up to 50 percent ad valorem duties may under certain circumstances be imposed by presidential proclamation when the President finds that the public interest so requires because any foreign country imposes any unequal imposition or discrimination upon the commerce of the United States or that any benefits accrue or are likely to accrue to any industry in any foreign country as a result of such imposition or discrimination imposed by any foreign country other than the foreign country in which the industry is located such that the duties may be imposed on “articles wholly or in part the growth or product of any such industry as he shall determine will offset such benefits. . . ”18 Notably, the limits of Section 338 have not been tested, and as such, President Trump may choose to proceed with his proposed tariffs or duties under other legal bases such as IEEPA, according to which he may argue broader legal authority to impose tariffs on individual countries or possibly a universal duty.19

Section 301 of the Trade Act of 197420

Section 301 investigations allow the United States Trade Representative (USTR) to enforce U.S. rights under trade agreements when a trading partner is acting inconsistently with their treaty obligations.21 The USTR has broad authority for a range of responsive actions to resolve unfair trade practices, including imposing duties or other restrictions on imports, withdrawing or suspending trade agreement concessions, or entering into a binding agreement with the foreign government to either eliminate the conduct in question or compensate the United States with satisfactory trade benefits.22

Under President Trump’s first administration, six new Section 301 investigations were initiated.23 While domestic industries may petition the USTR to initiate an investigation, these Section 301 investigations were exclusively initiated by the executive branch under the previous Trump administration. For example, in 2017, an investigation into technology transfer from China was initiated after the USTR received a memorandum directive from President Trump.24 The subsequent investigation resulted in the imposition of additional tariffs, ranging from 7.5% to 25%, on approximately $370 billion worth of U.S. imports from China.25

Section 301 provides a President with broad discretion to resolve unfair trade practices. Accordingly, we expect the incoming Trump administration will act under Section 301 such that the trend of more frequent Section 301 investigations is likely to continue.

Section 232 of the Trade Expansion Act of 196226

Through Section 232 investigations, the President may impose restrictions on certain imports where Commerce determines that the imports are entering into the United States “in such quantities or under such circumstances as to threaten to impair the national security.”27 After a Section 232 investigation, Commerce reports its findings to the President, including whether an article is being imported under circumstances that threaten to impair national security, along with any recommendations for action or inaction.28 After receiving Commerce’s report, the President determines what action to take to remedy the import of the article so that it no longer threatens national security.29

Like Section 301 investigations, Section 232 investigations may be initiated by the executive branch, or in response to industry petitions to Commerce, although the investigations and their outcomes depend heavily on the discretion of the executive branch and thus are sometimes viewed as more political than other trade remedy possibilities.30 In President Trump's first administration, Commerce conducted eight Section 232 investigations.31 Two investigations, which led to presidential proclamations imposing tariffs on imports, were prioritized after initiation at the request of President Trump.32 President Trump instructed Commerce to determine the effects on national security of steel and aluminum imports in accordance with Section 232 investigations as to imports of steel and aluminum.33 Those Section 232 investigations concluded with the imposition of 25 percent tariffs on steel imports and 10 percent tariffs on aluminum imports.34 The Section 232 tariffs on steel and aluminum are largely still in place.35 The six other Section 232 investigations, which were either initiated by Commerce or through domestic industry petitions during President Trump's first administration, did not ultimately result in the imposition of tariffs.36 It is likely that President Trump's second administration will continue to use Section 232 as a remedy more frequently in the future, using a broad definition of national security.37

Antidumping and Countervailing Duty Investigations38

While the previously mentioned trade remedies rely heavily on executive branch action and discretion, antidumping (AD) and countervailing duty (CVD) investigations continue to be a prominent remedy sought by U.S. domestic industries represented by private law firms which assist them in bringing AD and/or CVD petitions before the Commission or Commerce. AD and CVD investigations address unfair trade practices by providing relief to domestic industries as a matter of law where the industry is injured, threatened with injury, or the establishment of an industry is materially retarded due to imports being sold in the U.S. at less than fair value in AD investigations or subsidized by a foreign government in CVD investigations.39

Before duties are imposed, the Commission must find that the imports are a cause of material injury (or threat thereof) to the U.S. industry. The statute defines “material injury” as harm that is more than inconsequential, unimportant, or immaterial. In making this determination, the

Commission considers, among other economic factors, the volume of subject imports (including their share of the U.S. market), the impact of the imports on U.S. prices, and the impact of the imports on U.S. production and profits.40

Domestic industries may also bring AD and/or CVD petitions when an industry in the United States is materially retarded by reason of imports.41 The material retardation standard is particularly well suited for initiating investigations where a U.S. industry wants to establish or expand production, but they have been unable to do so due to unfair low prices of imports. Currently, Buchanan is the only law firm with active investigations alleging material retardation. Although the provision is little used, it provides an important route to trade relief for nascent domestic industries.

The remedies achieved in AD and/or CVD investigations are often long-lasting, with duties remaining in place for a decade or longer as Commerce conducts administrative reviews to assess duty rates and with five-year reviews undertaken by the Commission and Commerce. There are currently a historically large number of AD and CVD investigations pending before Commerce and the Commission and there is no reason to believe that domestic industries will slow the pace of seeking trade relief during President Trump's second administration.

Ultimately, President Trump's second administration will continue to utilize a variety of trade remedies when it seeks to provide U.S. industries with trade relief and works to achieve trade policy goals. While the macroeconomic effects of tariffs should certainly be considered, domestic industries will likely find that many of the Trump administration's trade actions are calibrated with their interests in mind.

Buchanan has a team of international trade and national security attorneys, and government relations professionals ready to help U.S. manufacturers with U.S. trade remedy laws and trade policy.

Gavin Bade, Decoding Trump's Tariff Threats, Politico Nightly, (Dec. 6, 2024), https://www.politico.com/newsletters/politico-nightly/2024/12/06/decoding-trumps-tariff-threats-00193118; Donald Trump (@realDonaldTrump), Truth Social (Nov. 25, 2024), https://truthsocial.com/@realDonaldTrump/posts/113546215051155542.

See 19 U.S.C. § 2132.

See 19 U.S.C. § 1338.

Clark Packard and Scott Lincicome, Presidential Tariff Powers and the Need for Reform, CATO Inst. (Oct. 9, 2024), https://www.cato.org/briefing-paper/presidential-tariff-powers-need-reform (noting that Section 338 has never been used to impose tariffs but indicating that "[a] private party or the executive branch may petition the US International Trade Commission (USITC) to initiate a Section 338 investigation.") It should be noted, however, that Section 338 itself does not explicitly indicate a private right to petition the Commission to initiate a Section 338 investigation. See generally John K. Veroneau & Catherine H. Gibson, Note, Presidential Tariff Authority, 111 AM. J. INT'L L. 957, 961-65 (2017). See also United States Tariff Commission, Twenty-first Annual Report of the United States Tariff Commission, at 38 (1937).

See 19 U.S.C. § 2412(a)(1).

See 19 U.S.C. § 1862(b)(1).

50 U.S.C. §1701 et seq.

See 50 U.S.C. §1701(a)

Packard and Lincicome, supra note 4; Warren Maruyama et al., Making Tariffs Great Again: Does President Trump Have Legal Authority to Implement New Tariffs on U.S. Trading Partners and China?, Center for Strategic and International Studies (Oct. 10, 2024), https://www.csis.org/analysis/making-tariffs-great-again-does-president-trump-have-legal-authority-implement-new-tariffs.

Statement from the President Regarding Emergency Measures to Address the Border Crisis (May 30, 2019), https://trumpwhitehouse.archives.gov/briefings-statements/statement-president-regarding-emergency-measures-address-border-crisis/.

Donald Trump (@realDonaldTrump), X (Jun. 7, 2019), https://x.com/realdonaldtrump/status/1137155056044826626; See also Packard and Lincicome, supra note 4.

See 19 U.S.C. § 2132.

See id. § 2132(a)(1).

See 19 U.S.C. § 2132(a)(3)(A). It should be noted that the President also has authority under this statute to put in place temporary import quotas "(i) only if international trade or monetary agreements to which the United States is a party permit the imposition of quotas as a balance-of-payments measure, and (ii) only to the extent that the fundamental imbalance cannot be dealt with effectively by a surcharge proclaimed pursuant to subparagraph (A) or (C)."

Id. § 2132(a).

See 19 U.S.C. § 1338.

See id. § 1338(a)(1)-(2), (d).

See id. § 1338(e).

See also Packard and Lincicome, supra note 4.

See 19 U.S.C. §§ 2411 et seq.

See 19 U.S.C. § 2411.

Id. § 2411(c)

Cong. Rsch. Serv., IF11346, Section 301 Of The Trade Act Of 1974 [hereinafter Section 301 Investigations]. Prior to President Trump's first administration, the last Section 301 investigation which resulted in tariffs was in 2009.

Initiation of Section 301 Investigation; Hearing; and Request for Public Comments: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 82 Fed. Reg. 40,213 (Aug. 24, 2017)

Section 301 Investigations, supra note 23; See, Notice of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 83 Fed. Reg. 40,823 (Aug. 16, 2018); Notice of Modification of Section 301 Action: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 85 Fed. Reg. 3,741 (Jan. 22, 2020).

See 19 U.S.C. § 1862.

See id. § 1862(b)(3)(A), (c)(1)(A)(i)-(ii).

Id.

See id. § 1862(c)(1).

See id. § 1862(b)(1), (c)(1).

See Cong. Rsch. Serv., R45249, Section 232 Investigations: Overview and Issues for Congress 2 (2021) [hereinafter Section 232 Investigations].

Id. at 1; See also Ting-Ting Kao, The Trump Effect: Section 232 and Challenges to the Dispute Settlement Body at the World Trade Organization, 51 Geo. Wash. Int'l L. Rev. 653, 654 (2019).

Memorandum on Steel Imports and Threats to National Security, daily Comp. Pres. Doc. (Apr. 20, 2017), chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.govinfo.gov/content/pkg/DCPD-201700259/pdf/DCPD-201700259.pdf.; Memorandum on Aluminum Imports and Threats to National Security, daily Comp. Pres. Doc. (Apr. 27, 2017), chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.govinfo.gov/content/pkg/DCPD-201700284/pdf/DCPD-201700284.pdf.

Section 232 Investigations, supra note 31, at summary (2021).

Maruyama, supra note 9.

See Section 232 Investigations, supra note 31, at 1, 16, 18-24 (2021); see also Proclamation No. 9888 of May 17, 2019: Adjusting Imports of Automobiles and Automobile Parts Into the United States, 84 Fed. Reg. 23,433, 23,435 (May 21, 2019); see also Bureau of Industry and Security, The Effect of Imports of Vanadium on the National Security (Feb. 22, 2021), chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.bis.doc.gov/index.php/documents/section-232-investigations/2793-vanadium-section-232-report-public-with-appendices/file.

See, e.g., U.S. Dep't of Commerce, Bureau of Industry and Security, The Effect of Imports of Steel on the National Security 1, (January 11, 2018). "[T]he Secretary in this investigation determined that 'national security' for purposes of Section 232 includes the 'general security and welfare of certain industries, beyond those necessary to satisfy national defense requirements, which are critical to minimum operations of the economy and government.'"

See 19 U.S.C. § 1671; 19 U.S.C. § 1673.

See 19 U.S.C. § 1671d(b)(1); 19 U.S.C. § 1673d(b)(1).

See 19 U.S.C. § 1677(7).

19 U.S.C. § 1671(a)(2)(B); 19 U.S.C. § 1673(2)(B).

Article Title: Protecting ERISA Retirement Plans From Cyber Threats: How To Mitigate Losses and Personal Liability

Category: Cybersecurity& Data Privacy

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Date: 1/21/25

Link: https://www.bipc.com/protecting-erisa-retirement-plans-from-cyber-threats-how-to-mitigate-losses-and-personal-liability?utm_source=advisory&utm_medium=email&utm_campaign=2025-01-16_Cybersecurity

Summary: In the past fifteen years, the rise of identity theft, ransomware, and data breaches has led to billions of exposed or stolen financial data records. Cybercriminals are thriving in vulnerable sectors that are target-rich but cybersecurity-poor.

ERISA does not explicitly address whether data is a plan asset needing protection, but recent DOL guidance emphasizes the importance of cybersecurity. Failure to protect plan assets can lead to costly litigation for fiduciaries due to breaches of their duties, and personal liability may arise from non-compliance.

Learn more about the proactive measures fiduciaries should take to fulfill their duties and protect plan assets and personal financial data.

Article: Over the past fifteen years, global business markets entered a new paradigm where identity theft, ransomware, email compromises, and data breaches are becoming more frequent, sophisticated, and costly. Billions of financial data records have been exposed or stolen, and billions more will follow. Cybercriminals are thriving in vulnerable sectors that are target-rich but cybersecurity-poor.

In the U.S., the 42 trillion dollars held in plans governed by the Employee Retirement Income Security Act (ERISA) depend not only on the investment performance of their assets but also on the integrity of the security systems of asset custodians and information technology (IT) departments and vendors who guard plan data and plan operations. Historically, retirement plan

fiduciaries took appropriate measures to ensure retirement funds were available to pay promised benefits to participants. In today's cyber-active world, fiduciaries must also take adequate measures to protect personal financial information and underlying IT systems from malicious cyber actors seeking to steal valuable assets, personal financial data, and other confidential information.

The interests at stake, based on the number of participants in ERISA plans and the concentration of wealth contained in those plans, are enormous. The trillions in ERISA plans are a primary source of income security for millions of Americans. Despite these stakes, long before the ubiquity of computers, ERISA's 1974 enactment only explicitly protected plan assets in private company plans; ERISA does not address whether data is a plan asset that requires protection. In this vacuum, recent Department of Labor (DOL) guidance recognized the importance of protecting plan assets and financial information from cyber threats. Failure to safeguard plan assets can result in costly litigation for corporate plan sponsors and plan fiduciaries derived from allegations of breach of the fiduciary duties of prudence and loyalty. Even without fully litigating the dispute, in today's online/social media world, mere allegations of corporate malfeasance concerning plan assets could be equally as costly. Fiduciaries hold significant control over the safety and integrity of a plan's assets; compliance with ERISA fiduciary duties requires shielding plan assets from cyber threats. Recommended plan management should mean taking action to protect personal financial data maintained at the plan level from cyber criminals. If plan fiduciaries fail to comply with strict ERISA duties regarding a plan's assets, they can be found personally liable for breaches of their fiduciary obligations. Whether a company's fiduciary insurance or cyber insurance policies will defend and provide insurance coverage for the plan fiduciaries for this type of claim will first depend on whether the company has even purchased these types of insurance policies for the ERISA Plan and if so, whether the coverage is sufficient to cover plan losses.

Already reported in ERISA class action lawsuits alleging fiduciary breaches for failure to safeguard plan assets are cases with allegations of failure to protect confidential personal financial information. Safeguarding the sensitive personal financial data contained in ERISA accounts from cyber threats presents a unique challenge. No federal statute specifically addresses cybersecurity protection of electronic records.

There are several proactive measures fiduciaries should take to fulfill their duties and protect plan assets and personal financial data:

Conduct Regular Risk Assessments: Fiduciaries should routinely evaluate cybersecurity risks that can impact plan participants' information. For large ERISA recordkeepers and custodians, this includes all IT systems "corresponding" with such data/information. Examples of such evaluations include performing system vulnerability scans, penetration testing, reviewing

network and data access controls to ensure only authorized personnel can access sensitive information, and conducting annual third-party security system audits.

Engage With Service Providers: Many retirement plans rely on third-party service providers. Plan sponsors should thoroughly vet and partner only with service providers that adhere to stringent cybersecurity standards. Contracts should outline the provider's data protection protocols and include breach notifications and liability terms. Remember, fiduciaries can be held liable not only for failing to protect information but for failing to monitor third parties.

Implement Multi-Factor Authentication (MFA): One of the simplest and most effective ways to enhance data security is to require MFA to access sensitive data. This includes MFA for participant access to individual accounts and for any entity, whether fiduciary or not, to access plan-wide data. This ensures access to financial data is more secure and less susceptible to unauthorized access.

Adopt Data Encryption Practices: Data at rest and in transit should be encrypted to prevent unauthorized access. Fiduciaries should ensure their systems employ the latest encryption technology and that service providers and partners follow similar practices, as there are often logical connections between networks.

Training and Awareness Programs: Employees, participants, fiduciaries, and anyone accessing an IT system holding retirement information should receive ongoing training on identifying protected data and securing it, cybersecurity best practices, avoiding 'phishing' messages, and other security risks.

Develop a Breach Response Plan: Fiduciaries should have a comprehensive cyber incident response plan developed by organizational stakeholders and exercised regularly. There is no defense to a breach that compares to knowing what to do in the event of a breach. A cyber incident response plan should include notifying affected participants (including making notifications in the absence of normal work communications), working with internal and external cybersecurity experts, and correcting system weaknesses that led to the breach.

Best Practices for Plan Sponsors to Ensure Fiduciary Compliance

To enhance fiduciary protection of retirement plan data, plan sponsors should ensure their fiduciaries follow appropriate cybersecurity standards recommended by the Department of Labor (DOL) and retirement industry experts:

DOL Guidance: The DOL provides guidance on cybersecurity best practices for retirement plans. Fiduciaries should be familiar with these guidelines, including robust security protocols, strong access controls, and regular monitoring of data security measures. If they do not follow these guidelines, they should use other standards commonly accepted by organizations in the retirement industry.

Cybersecurity Risk Management: Fiduciaries should develop comprehensive cybersecurity programs that align with risk management standards. This includes performing third-party cybersecurity audits and benchmarking cybersecurity practices against appropriate standards.

Vendor Management: Contracts with third-party vendors handling sensitive data should include clearly defined security obligations, service-level agreements regarding data protection, incident response protocols, and identify consequences for failure to adhere to obligations. Determine if the service provider is cross-marketing the data of participants, which puts it at additional risk of cyber theft.

Regular Plan Reviews: Sponsors should encourage fiduciaries to regularly review and update their cybersecurity protocols to keep up with evolving threats. This should include updating firewalls, strengthening access controls, and regularly testing cybersecurity measures.

Periodic Training Sessions: Plan participants should be trained regularly on cybersecurity threats and measures to mitigate risks for themselves and others. A well-informed first line of defense is less likely to fall prey to phishing attempts, social engineering, and other cyberattacks.

Fiduciaries have a legal and ethical responsibility to ensure retirement assets are well-protected from the rising tide of cyber threats. If they fail in this duty, they can be held personally liable for plan losses. By adhering to robust cybersecurity practices, conducting regular risk assessments, and following DOL-recommended guidelines, fiduciaries can shield plan participants from identity theft, hacking, and data breaches. Retirement plan participants should engage their fiduciaries and demand transparency, vigilance, and robust measures to protect the plan participants' assets from cybersecurity breaches and theft.

With enhanced cybersecurity measures, including taking proactive steps to ensure the safety and integrity of plan participant's hard-earned assets in an increasingly digital world, plan fiduciaries can mitigate the risk of personal liability.

Article Title: FCC's New TCPA One-to-One Consent Rules Effective January 27: What Companies Need To Know

Category: Litigation

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Date: 1/23/25

Link: https://www.bipc.com/fccs-new-tcpa-one-to-one-consent-rules-effective-january-27-what-companies-need-to-know?utm_source=advisory&utm_medium=email&utm_campaign=2025-01-22_Cybersecurity

Summary: In December 2023, the Federal Communications Commission implemented new regulations to address the "lead generator loophole" in the Telephone Consumer Protection Act, effective January 27, 2025.

These rules require marketers to obtain a separate written consent for each partner or affiliate who may contact a consumer via automated telephone or text.

To ensure compliance with these new regulations by the upcoming effective date, telemarketers and sellers should familiarize themselves with the updated requirements.

Article: *Update: On January 24, 2025, the FCC issued an order postponed the effective date of the one to one rule to January 26, 2026, or until, following a decision from the Eleventh Circuit a petition challenging the rule, the Commission issues a Public Notice specifying a sooner date.

In December 2023, the Federal Communications Commission (FCC) implemented new regulations to address the "lead generator loophole" in the Telephone Consumer Protection Act (TCPA), effective January 27, 2025*. These rules mandate that sellers, callers, and lead generators must obtain individual consent from consumers before contacting them, significantly altering how consent is acquired.

Key Takeaways

Prior Express Written Consent (PEWC): The new rules require that consent must be obtained for each individual seller rather than through a single agreement covering multiple companies. The FCC has redefined PEWC to mean a written agreement that specifies one seller and ensures calls or texts are relevant to the consent given.

Scope of Consent: The consent must be "logically and topically associated" with the service or product offered. This term is not defined in the new rule, creating risk for tele marketers seeking to avail themselves of this exception, especially at first.

Compliance Adjustments: Lead generators and website operators will need to modify their platforms to secure individual consents for each seller if they are using any kind of automatic dialing system (ATDS) or artificial voice messages.

Consent Workflow on Paper Consent and Web Forms: Websites can implement checkboxes allowing consumers to select multiple sellers for contact, thereby obtaining one-to-one consent efficiently.

Proof of Consent: The burden of proof for retaining records and demonstrating valid consent lies with the caller or texter, and consent must come directly from the consumer and cannot be sold or transferred.

To align with the new regulations by the effective date*, telemarketers and sellers should:

Update contracts to require one-to-one consent and ensure that lead generators being used are in compliance.

Ensure lead generator vendor contracts include indemnification for breaches regarding consent.

Review webforms to confirm compliance with the new consent requirements.

Establish clear responsibilities for record-keeping between parties.

Implement audits to ensure ongoing compliance with the new rules.

As most telemarketers know well, TCPA compliance risk extends far beyond FCC enforcement: those in violation (or possible violation) could find themselves subject to a class action lawsuit alleging millions of dollars in statutory damages.

Article Title: Navigating the FDA's Final Interim Policy on Compounding with Bulk Drug Substances: A Guide for 503A Pharmacies and 503B Outsourcing Facilities

Category: Life Sciences

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Link: https://www.bipc.com/navigating-the-fda-final-interim-policy-on-compounding-with-bulk-drug-substances-a-guide-for-503a-pharmacies-and-503b-outsourcing-facilities?&utm_source=advisory&utm_medium=email&utm_campaign=2025-01-21_LifeSciences

Summary: The FDA issued final interim guidance on compounding practices involving bulk drug substances. This policy represents the FDA's ongoing efforts to strike a balance between patient access to necessary compounded medications and the need to ensure these products are safe and effective. It also underscores the agency's increasing oversight of compounding practices.

For 503A and 503B compounders, understanding the key aspects of this guidance, the risks, and how to remain compliant is critical for thriving while ensuring patient safety.

Article: he U.S. Food and Drug Administration (FDA or “the Agency”) has issued a final interim guidance on compounding practices involving bulk drug substances. This policy represents the FDA’s ongoing efforts to strike a balance between patient access to necessary compounded medications and the need to ensure these products are safe and effective. The policy also underscores the agency’s increasing oversight of compounding practices.

Understanding the key aspects of this guidance, the risks it highlights, and how to remain compliant is critical for 503A and 503B compounders that aim to thrive while ensuring patient safety.

Understanding the FDA’s Interim Policy

The FDA’s guidance, titled Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act, outlines specific conditions under which pharmacies can compound medications using bulk drug substances.

Effective January 7, 2025, the FDA will no longer categorize newly nominated bulk drug substances into interim categories, such as Category 1. This change carries significant implications for compounders under sections 503A and 503B. Pharmacies may no longer compound with newly proposed bulk drug substances unless and until the FDA completes its review process and includes the substance on its final bulk drug substance list. This process, which involves evaluations by the FDA’s Pharmacy Compounding Advisory Committee (PCAC), consultation with the United States Pharmacopeia (USP), public commentary through notices in the Federal Register, and a determination by the FDA that the substance meets statutory and regulatory requirements, can take several years to complete.

For substances currently listed in Category 1, compounders may continue using these bulk drug substances until the FDA either finalizes their inclusion on the approved list or formally declines to include them. However, the new policy effectively halts interim compounding for substances that have been nominated but not yet reviewed or approved for inclusion on the lists.

The FDA has stated that it will continue developing the bulk drug substance lists on a rolling basis, which means new substances can still be nominated for review. However, there is no set timeline for when a nominated substance will be evaluated, leaving compounders in a position

where they must closely monitor PCAC agendas and public notices to stay informed about the status of substances they rely on for compounding.

By eliminating the interim compounding process for new substances, the FDA reinforces its commitment to ensuring that only thoroughly reviewed and approved bulk drug substances are used in compounded medications. This places additional burdens on compounders, requiring them to be diligent in tracking regulatory developments while maintaining compliance with evolving guidance.

Implications for Compounders

The FDA's interim policy signals a trend toward heightened regulatory scrutiny for both 503A traditional compounding pharmacies and 503B outsourcing facilities. Compliance with these new expectations presents a range of challenges, particularly in the context of the Agency's increased focus on oversight and enforcement.

503B outsourcing facilities, in particular, face the added challenge of complying with current Good Manufacturing Practices (CGMP). The FDA has made it clear that even minor deviations from CGMP can have significant consequences, including product recalls, warning letters, and monetary penalties. This means that 503B outsourcing facilities must dedicate substantial resources to ensuring their processes, facilities, and documentation meet these stringent standards.

Another critical challenge for both 503A and 503B compounders is the growing complexity of supply chain oversight and documentation. Compounders must ensure that all bulk drug substances are sourced from FDA-registered facilities that meet quality and safety standards. Additionally, they must maintain meticulous documentation, including supplier qualifications, certificates of analysis, and clinical justifications for each substance used. Any lapses in these areas could result in enforcement actions that disrupt operations and compromise patient safety.

Strategies for Compliance

Compliance with the FDA's interim policy and other regulatory expectations requires a proactive and comprehensive approach.

1. Gap Analysis

One effective strategy is to conduct a regulatory gap analysis, which involves regularly evaluating all aspects of a pharmacy's operations to identify potential vulnerabilities. By addressing these gaps before they lead to compliance issues, compounders can mitigate risks and avoid costly enforcement actions.

2. Robust Policies & Procedures

Developing and maintaining robust policies and procedures is another crucial component of regulatory compliance. Compounders should establish clear protocols for verifying drug shortage statuses, documenting clinical justifications, and ensuring quality control in all compounding practices. These procedures must align with FDA guidance and be consistently followed by all staff members.

3. Strong Supply Chain Oversight

Strengthening supply chain oversight is equally important. Compounders should establish strong relationships with FDA-registered suppliers and regularly check in with these suppliers to ensure the quality and safety of the bulk drug substances they provide. This level of oversight helps reduce the risk of introducing non-compliant or substandard substances into the compounding process.

4. Training

Staff training is another essential area of focus. Pharmacists and technicians must stay informed about evolving FDA policies, CGMP requirements, and best practices in compounding. Regular training sessions ensure that all staff members understand their responsibilities and are equipped to meet regulatory expectations.

Navigating Legal Risks Post-Tirzepatide Shortage Removal

Despite the challenges posed by increased regulatory scrutiny, 503A pharmacies and 503B outsourcing facilities remain a vital part of the healthcare system. They fulfill a critical role by providing customized medications for patients whose needs cannot be met by commercially available products. For example, patients with allergies to specific excipients or those requiring tailored dosages rely on compounded medications to manage their conditions effectively.

The importance of compounded medications has been particularly evident during drug shortages when pharmacies must act quickly to fill gaps in the availability of essential medications.

However, recent developments surrounding tirzepatide highlight a growing challenge for compounders. Compounders of tirzepatide were left reeling as FDA, in short order, determined that the tirzepatide shortage was resolved, retracted that decision, and then subsequently reasserted that the shortage was, in fact, resolved. In the wake of this final decision, pharmaceutical companies have issued more cease-and-desist letters to compounding pharmacies, 503B outsourcing facilities and telemedicine providers following the FDA's decision. Compounders and prescribers must be cognizant of the current regulatory and legal landscape, and exercise great care when responding to these letters. A thoughtful and strategic approach is critical to mitigating potential legal risks while preserving the ability to meet patient needs.

Conclusion

The FDA's final interim policy on compounding with bulk drug substances presents both challenges and opportunities for 503A and 503B compounders. While compliance requires significant effort and resources, it also provides an opportunity for compounders to demonstrate their commitment to patient safety and high-quality care.

By staying informed, investing in staff training, implementing robust policies and procedures, and seeking expert guidance, compounders can navigate the evolving regulatory landscape with confidence. These efforts not only ensure compliance with FDA expectations but also reinforce the trust that patients and healthcare providers place in compounding pharmacies as vital contributors to personalized patient care.

How Buchanan Can Help

For compounders navigating the complexities of the FDA's interim policy, having access to reliable legal and regulatory support is essential. Buchanan's FDA attorneys specialize in representing 503A pharmacies and 503B outsourcing facilities, offering tailored solutions to help them meet regulatory expectations while continuing to deliver high-quality care to their patients.

We assist compounders with a wide range of compliance and operational challenges, including preparing for FDA inspections, responding to warning letters, and developing policies that align with current guidance. If your pharmacy needs assistance with compliance, FDA inspections, or other regulatory matters, we are here to help. Contact us today to learn more about how we can support your practice.

Article Title: FDA Grants Marketing Order for ZYN Nicotine Pouches

Category: Life Sciences

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Link: https://www.bipc.com/fda-grants-marketing-order-for-zyn-nicotine-pouches?&utm_source=advisory&utm_medium=email&utm_campaign=2025-01-22_LifeSciences

Summary: On January 16, the U.S. Food and Drug Administration issued a marketing granted order for 20 ZYN nicotine pouch products.

The FDA concluded that the premarket tobacco product application for these products provided sufficient evidence to meet the public health standards mandated by the 2009 Family Smoking Prevention and Tobacco Control Act.

This marketing authorization represents a significant milestone, as it is the first time the FDA has approved products commonly known as nicotine pouches for marketing in the United States.

Article:

On January 16, the U.S. Food and Drug Administration (FDA) issued a marketing granted order (MGO) for 20 ZYN Nicotine Pouch products. This marketing authorization, which was based upon a premarket tobacco product application (PMTA), marks the first instance that FDA has authorized products commonly referred to as nicotine pouches to be marketed in the U.S.

The PMTA pathway, which is only one of three pathways to market a new tobacco product, requires FDA to conclude, among other things, that permitting the product to be marketed would be "appropriate for the protection of the public health" (APPH). In issuing the MGO, FDA officials stated the evaluation of the PMTA showed that, "the authorized products pose lower risk of cancer and other serious health conditions [. . .]." FDA also highlighted evidence showing: (1) the appeal and likelihood to buy the authorized products was low among former tobacco users and never-users, including those ages 18-24; and (2) the authorized products have the potential to help a substantial proportion of adult cigarette and/or smokeless tobacco product users stop or reduce using such products. Due to this, among other factors, permitting the marketing of the ZYN Nicotine Pouches, subject to certain marketing restrictions, was deemed to be APPH.

Navigating Stringent Marketing Restrictions Imposed

Though the marketing of the ZYN Nicotine Pouches was deemed to be APPH, FDA clarified that no express or implied statements or representations of FDA approval could be made on or through any label, labeling, media, or advertising. FDA also emphasized that explicit or implicit modified risk claims cannot be made without a modified risk tobacco product application.

Additionally, FDA imposed stringent marketing restrictions including "measures to ensure ads are carefully targeted to adults ages 21 and older and the demographics of the audiences reached by the ads are tracked and measured by the manufacturer." FDA also expressed support for certain aspects of the marketing practices outlined in the PMTA intended to restrict or otherwise to reduce potential youth access and exposure to labeling and advertising. Moreover, FDA recommended the taking of additional steps to limit youth exposure to print and point-of sale advertising such as "limiting advertising to print publications where 85% or more of the readership is 21 years of age or older and/or selecting publications that do not over-index for youth."

The Road Ahead: Stricter Oversight and Compliance Expectations

The decision to authorize the marketing of ZYN Nicotine Pouches, along with the recent issuance of a Proposed Rule that would limit the level of nicotine in certain tobacco products, makes clear that FDA intends to exercise stricter oversight over how such products are marketed and sold, which may include pursuing potential enforcement. On a positive note, however, this authorization clarifies that FDA recognizes nicotine pouches are in fact a less harmful alternative to combusted cigarettes and have a role to play in reducing the use of such products by adults. Likewise, this authorization makes clear that successful submission of PMTAs for nicotine pouches is possible.

The experienced and uniquely qualified FDA and Government Relations teams at Buchanan are available to discuss these recent developments and address questions regarding the regulation of tobacco products.

Article Title: Tirzepatide, FDA, and Compounding: Understanding the Current Landscape

Category: Life Sciences

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Date:1/27/25

Link: https://www.bipc.com/tirzepatide-fda-and-compounding-understanding-the-current-landscape?&utm_source=advisory&utm_medium=email&utm_campaign=2025-01-22_LifeSciences

Summary: The removal of tirzepatide from the drug shortage list of the Food and Drug Administration list in late 2024 marked a significant turning point for compounders in both 503A and 503B industries.

With its unique position as a drug in high demand for various therapeutic purposes, tirzepatide has brought to light critical issues within the regulatory framework for 503A and 503B compounders.

As regulatory scrutiny intensifies, compounders must carefully navigate a landscape defined by FDA enforcement discretion, legal challenges, and evolving compliance requirements.

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The removal of tirzepatide from the drug shortage list of the Food and Drug Administration (FDA) list in late 2024 marked a significant turning point for compounders in both 503A and 503B industries. With its unique position as a drug in high demand for various therapeutic purposes, tirzepatide has brought to light critical issues within the regulatory framework for 503A and 503B compounders. As regulatory scrutiny intensifies, compounders must carefully navigate a landscape defined by FDA enforcement discretion, legal challenges, and evolving compliance requirements.

The Impact of FDA’s Drug Shortage Determination

FDA's decision to remove tirzepatide from its drug shortage list has fundamentally altered the regulatory playing field for 503A compounding pharmacies and 503B outsourcing facilities. While the drug was listed as in shortage, 503A and 503B compounders were permitted to compound tirzepatide under conditions that allowed them to bypass certain restrictions related to

commercially available products. This enabled compounders to meet the needs of patients when commercially manufactured supplies could not keep pace with demand.

However, the removal of tirzepatide from the shortage list has placed compounders under tighter restrictions. Under FDA regulations, compounders may not compound medications that are "essentially copies" of commercially available drugs unless a shortage or other exemption applies. With the shortage determination reversed, pharmacies compounding tirzepatide could be at risk of potential regulatory enforcement, facing potential FDA enforcement actions as well as legal challenges from the manufacturers.

FDA's Enforcement Discretion

In the wake of tirzepatide's shortage announcement, FDA clarified that it will exercise enforcement discretion during its ongoing litigation with the Outsourcing Facilities Association (Outsourcing Facilities Association v. United States Food and Drug Administration) and later issued an official statement for its current position on enforcement discretion and winding down for compounding.

FDA stated the following:

February 18, 2025 – End date for a 503A compounders to compound, distribute, or dispense tirzapetide.

March 19 2025 – End date for a 503B compounders to compound, distribute, or dispense tirzapetide.

This means that while FDA does not currently plan to take action against compounders preparing tirzepatide, this discretion has clear boundaries. Additionally, compounders must meet strict quality and safety standards, and any significant deviations from these requirements may prompt regulatory intervention.

FDA's enforcement discretion applies uniformly to both 503A compounding pharmacies and 503B outsourcing facilities, regardless of whether they are directly involved in the litigation. However, the agency has emphasized that this discretion is temporary and could be withdrawn based on the outcome of the OFA case or other regulatory developments. This underscores the importance of compliance, as pharmacies operating under the assumption of continued discretion may face unexpected enforcement actions if circumstances change.

Legal Risks and Manufacturer Pushback

One of the most immediate consequences of tirzepatide's removal from the shortage list has been an increase in legal challenges. The manufacturers of GLP-1 drugs have taken steps to protect their intellectual property by filing lawsuits or taking other legal actions against entities compounding or distributing unapproved versions of tirzepatide for other violations of the law. These legal actions highlight the risks that compounding pharmacies face when their operations intersect with commercially available products.

For example, a federal judge ordered a compounding entity to cease its production of tirzepatide, citing trademark infringement and concerns about the potential confusion caused by unapproved compounded versions. These lawsuits serve as a warning to compounding pharmacies about the importance of staying within the boundaries of FDA regulations and other applicable laws.

Regulatory and Compliance Considerations for Compounders

The removal of tirzepatide from the shortage list has shifted the regulatory focus for compounders from short-term solutions to long-term compliance strategies. Compounding pharmacies must now operate with heightened vigilance to ensure that their practices align with FDA requirements, particularly in the following areas:

1. Quality Assurance and Safety

FDA's enforcement discretion does not absolve pharmacies of their responsibility to maintain high standards of quality and safety. Pharmacies must ensure that compounded tirzepatide injections meet all applicable standards for sterility, potency, and labeling. Robust quality assurance programs, including regular testing and documentation, are essential to demonstrate compliance and avoid enforcement actions.

2. Sourcing Bulk Drug Substances

As we reported here, FDA has consistently emphasized the importance of sourcing bulk drug substances from reputable suppliers. Compounders must verify that their suppliers comply with FDA regulations and meet stringent quality standards. Any deviations from these standards could result in the compounded product being deemed unsafe or non-compliant.

3. Documentation and Recordkeeping

Thorough documentation is critical for demonstrating compliance with FDA regulations. Pharmacies should maintain detailed records of all compounding activities, including the sourcing of materials, preparation processes, and quality control measures. This documentation serves as both a compliance tool and a defense mechanism in the event of regulatory scrutiny or legal challenges.

4. Staying Informed About Regulatory Updates

As the regulatory landscape continues to evolve, compounding pharmacies must stay informed about changes in FDA policies and guidance. Regularly reviewing updates from FDA, industry associations, and legal experts can help pharmacies anticipate potential challenges and adapt their operations accordingly.

The Role of the OFA Litigation

The case centers on FDA's authority to regulate compounding activities and its decision-making process regarding instituting and ending drug shortages. Depending on the outcome, the case could set a precedent that impacts FDA's approach to regulating 503A and 503B pharmacies.

For now, FDA has opted to maintain enforcement discretion for all compounders, regardless of their involvement in the case. This approach provides some stability in the short term but leaves the long-term regulatory framework for tirzepatide compounding unresolved.

After the FDA removed tirzepatide from the drug shortage list, the Judge presiding over the OFA v. FDA case granted the NDA holder's motion to intervene as a defendant, allowing them to adequately represent their interests in the case. Additionally, in a hearing held on January 14, 2025, the Judge declined to issue a summary judgement and allowed the case to continue. That said, it is imperative that compounders must carefully monitor the progress of this litigation and be prepared to adjust their operations based on the court's rulings.

Broader Implications for the Compounding Industry

The regulatory and legal challenges surrounding tirzepatide have far-reaching implications for the compounding industry as a whole.

First, FDA's handling of tirzepatide highlights its commitment to balancing patient access with regulatory oversight. While enforcement discretion provides flexibility for compounders, it also signals the agency's intention to closely monitor compounding activities, particularly for high-demand drugs.

Second, the removal of tirzepatide from the shortage list has intensified competition between compounding pharmacies and pharmaceutical manufacturers. Manufacturers are likely to increase their efforts to protect their market share, potentially leading to more frequent legal challenges and heightened scrutiny of compounded medications.

Lastly, the challenges facing compounding pharmacies underscore the importance of industry advocacy. Organizations representing compounders must continue to engage with regulators and policymakers to ensure that the needs of pharmacies and patients are considered in the regulatory process. Collaborative efforts can help shape policies that balance safety with access to compounded medications.

Conclusion

The regulatory landscape for tirzepatide compounding is a microcosm of the broader challenges facing the compounding industry. FDA's decision to remove tirzepatide from the shortage list, coupled with its ongoing enforcement discretion and the legal challenges from manufacturers, underscores the need for compounding pharmacies to remain vigilant, compliant, and proactive.

By prioritizing quality, staying informed, and engaging in advocacy, compounding pharmacies can navigate these challenges and continue to provide patients with access to critical medications. As the industry adapts to these new realities, the lessons learned from tirzepatide will serve as a guide for future regulatory and operation.

How We Can Help

For compounders navigating the complexities of FDA's interim policy, having access to reliable legal and regulatory support is essential. Buchanan's FDA attorneys specialize in representing 503A pharmacies and 503B outsourcing facilities, offering tailored solutions to help them meet regulatory expectations while continuing to deliver high-quality care to their patients.

We assist compounders with a wide range of compliance and operational challenges, including preparing for FDA inspections, responding to warning letters, and developing policies that align with current guidance. If your pharmacy needs assistance with compliance, FDA inspections, or other regulatory matters, we are here to help. Contact us today to learn more about how we can support your practice.

Article Title: FinCEN Suspends CTA Enforcement Despite Supreme Court Ruling

Category: Corporate

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Link: https://www.bipc.com/supreme-court-allows-fincen-to-enforce-the-corporate-transparency-act?utm_source=advisory&utm_medium=email&utm_campaign=2025-01-24_Corporate

Summary: On January 23, 2025, the United States Supreme Court stayed the injunction granted by the United States District Court for the Eastern District of Texas in Texas Top Cop Shop v. Garland, which enjoined the Financial Crimes Enforcement Network (FinCEN) from enforcing the Corporate Transparency Act (CTA) nationwide.

However, FinCEN has indicated that it is still subject to a nationwide ban on the enforcement of the CTA under an order in a separate case in the United States District Court for the Eastern District of Texas challenging the enforcement of the CTA, Smith v. The United States Department of Treasury.

As a result, FinCEN noted in a statement on its website on January 24, 2025 that reporting companies are still not subject to liability if they do not file a beneficial ownership information report with FinCEN while the Smith order remains in effect.

Learn more about key takeaways and implications for reporting companies.

Article:

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As a result, FinCEN noted in a statement on its website on January 24, 2025 that reporting companies are still not subject to liability if they do not file a beneficial ownership information report with FinCEN while the Smith order remains in effect.

As described in our earlier advisory, the United States District Court for the Eastern District of Texas in Texas Top Cop Shop v. Garland issued a preliminary injunction enjoining FinCEN from enforcing the Corporate Transparency Act nationwide. The government appealed the district court's decision to the Fifth Circuit and filed an emergency motion for a stay of the injunction pending appeal. While the Fifth Circuit initially granted the government's emergency motion to stay the injunction, three days later the Fifth Circuit vacated that stay, leaving the district court's injunction in place.

The government then applied to the Supreme Court for a stay of the injunction, which it granted. The Supreme Court's stay is in effect until the disposition of the government's Fifth Circuit appeal and possibly later if a writ of certiorari is filed with the Supreme Court after the disposition of that appeal.

However, while the order in the separate Smith decision expressly enjoined FinCEN from enforcing the CTA against the two plaintiffs in that case and their entities, FinCEN has taken the position, presumably based upon other language in the order, that it imposes a nationwide ban on FinCEN's enforcement of the CTA.

In terms of future FinCEN action, if it becomes able to enforce the CTA, the nominee for Secretary of the Treasury, Scott Bessent, in response to questions raised during the Senate confirmation process, stated that he was "committed to reviewing the regulatory implementation of the CTA to ensure that Treasury meets the law's objective of combating illicit finance without unduly burdening small businesses as Congress directed."

We recommend that reporting companies continue to gather the information needed to file beneficial ownership information reports with FinCEN if and when they once again become obligated to do so.

Article Title: Understanding the FDA's Ban on Red Dye No. 3: Implications and Protective Measures for Companies

Category: Litigation

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Link: https://www.bipc.com/understanding-the-fda%E2%80%99s-ban-on-red-dye-no.-3-implications-and-protective-measures-for-companies?utm_source=advisory&utm_medium=email&utm_campaign=2025-01-23_Litigation

Summary: The U.S. Food and Drug Administration (FDA) has published an order to ban the use of FD&C Red No. 3, also known as erythrosine, in foods (including dietary supplements) and ingested drug products in the Federal Register through a rule published January 16, 2025, 90 Fed. Reg. 4628.

This ban presents potential challenges for manufacturers in the food and drug industries.

Learn more about takeaways for companies regarding the reasons for the ban, the implications and potential legal risks involved, and the steps they can take to protect themselves from liability, including challenging the ban.

Article:

The U.S. Food and Drug Administration (FDA) has published an order to ban the use of FD&C Red No. 3, also known as erythrosine, in foods (including dietary supplements) and ingested drug products in the Federal Register through a rule published January 16, 2025, 90 Fed. Reg. 4628. The order repeals the color additive regulations that permit the use of this dye. FDA's order will be effective January 15, 2027, for food products and January 18, 2028, for ingested drug products. The procedure is rulemaking on a formal record. FDA will accept objections to the order and requests for a hearing related to this order until February 18, 2025.

This article aims to inform companies about the reasons for the ban, the implications and potential legal risks involved, and the steps they can take to protect themselves from liability, including challenging the ban.

What is FD&C Red No. 3?

FD&C Red No. 3 (Red No. 3) has a long history in the food and drug industries, primarily used for its "cherry-red" color in products such as candies, desserts, and even medications. Although the FDA has convened advisory committees to investigate color additives in the past, banning FD&C Red No. 2 in 1976, Red No. 3 has survived decades of scrutiny. In 1992, the FDA first announced its intention to remove authorization for Red No. 3 based on findings related to its carcinogenic effects in male rats, as published in a study from 1987. This study gained renewed attention in 2023 when it was cited in a petition proposing that the FDA reevaluate the color additive regulations for Red No. 3, ultimately leading to the recent ban.

The FDA's recent ban is based on the Delaney Clause of the Federal Food, Drug, and Cosmetic (FD&C) Act, which prohibits any food or color additive that has been found to induce cancer in humans or animals. This prohibition must be read broadly to ban color additives that pose even de minimis or trivial risks to humans, as determined by the U.S. Court of Appeals for the D.C. Circuit in 1987.1

Although further evaluation of Red No. 3 was postponed when the case was decided in 1987, the precedent is particularly relevant to the FDA's decision today. When re-evaluating the original study linking Red No. 3 to cancer in rats, the FDA admitted that the study's relevance to humans is limited. The cancer observed in the study was attributed to a "rat-specific" hormonal mechanism, and the FDA noted that even the highest dietary exposure is far below the previously established acceptable daily intake. Because the study was found to induce cancer in animals, the FDA was required to repeal Red No. 3's authorization "as a matter of law" under the Delaney Clause. Nevertheless, the rulemaking on a formal record process can be lengthy. Factual and legal issues can exist that must be raised by Feb. 18.

Potential Impacts of the Ban

While the FDA's ban on Red No. 3 necessitates significant restructuring and reformulation of food and drug products that use the additive, it also carries potential legal consequences that manufacturers, distributors, and producers must be mindful of:

Regulatory Action: Under 21 U.S.C. § 348, food additives are only permissible if there is a regulation allowing their use. Products containing unapproved additives are considered "adulterated" and subject to regulatory action by the FDA. Companies that continue to market products with Red No. 3 after the effective dates of the order risk the potential seizure and condemnation of their products. This could lead to significant financial losses and disruptions in production.

Negligence Per Se: Including banned or dangerous food additives exposes manufacturers and distributors to negligence per se claims by private parties. Now that the Red No. 3 color additive regulations have been revoked, public interest groups may be empowered to seek recovery from companies that have used the additive.2

Failure to Warn Claims: Companies may face legal action for failing to warn consumers about the risks associated with products containing Red No. 3.3

Consumer Class Actions: The widespread use of Red No. 3 in various products increases the likelihood of consumer class action lawsuits, where affected consumers may band together to seek damages. These suits can be especially damaging as they often attract media attention and can result in substantial settlements or judgments.

Companies must also stay aware of additional state-specific regulations that may complicate compliance efforts, further exposing manufacturers to liability. Different states may have varying standards for food additives, as well as different remedies for consumers. Failure to comply with these regulations can lead to additional legal challenges.

How Can You Protect Yourself?

To minimize the risks associated with the FDA's ban on Red No. 3, companies should consider the following measures:

Begin Phasing Out Use of Red No. 3: Begin the process of reformulating products to eliminate Red No. 3. Companies are required to discontinue use of Red No. 3 in food products by January 15, 2027, and by January 18, 2028, for ingested drug products. Companies should explore alternative colorants that are both safe and compliant with FDA regulations.

Understand State-Specific Regulations: Be aware of any state-specific regulations that apply to your company and note that you may be subject to state regulations in all places where your products enter the stream of commerce. Companies should conduct a thorough review of state-specific food additive regulations to ensure they are not inadvertently violating any laws.

Determine Whether to Object to the Order: FDA is accepting objections to the order and requests for a hearing related to this order until February 18, 2025. Any objections and requests for hearing filed after February 18 will not be considered, so the time to act is now.

Monitor Legal Trends: Stay informed about legal trends related to FDA regulations and color additives, including any further procedures related to this Order. This vigilance can help you avoid future reformulation costs and potential legal challenges. Engaging with industry associations and legal experts can provide valuable insights into emerging trends and best practices.

Reassess Compliance: Conduct a thorough review of your compliance with all FDA regulations. Ensuring that your products meet current standards is essential for protecting your business. This may involve updating labeling, conducting safety assessments, and implementing quality control measures.

Consult Legal Experts: Engage with legal counsel specializing in food and drug law to navigate the complexities of compliance and liability. Their expertise can provide valuable insights and strategies for risk management. Regular consultations can help you stay ahead of regulatory changes and prepare for potential legal challenges.

Conclusion

The FDA's ban on Red No. 3 presents potential challenges for manufacturers in the food and drug industries. By understanding the implications of this decision and taking proactive steps to protect themselves, companies can mitigate the risks of product liability and ensure compliance with regulatory standards. If you have concerns about how this ban may impact your business or if you need assistance navigating these changes, we encourage you to contact one of our skilled attorneys. Our team of multi-disciplinary experts is here to provide the legal support and guidance you need to protect your interests in this evolving landscape.

Pub. Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987).

See, e.g., Pub. Citizen v. Foreman, 631 F.2d 969 (D.C. Cir. 1980).

See, e.g., Lavoie-Fern v. Hershey Co., 610 F. Supp. 3d 661 (M.D. Pa. 2022).

Article Title: White House Orders Pause of Agency Grant, Loan, and Financial Assistance Programs

Category: Government Relations & Public Policy

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Link: https://www.bipc.com/white-house-orders-pause-of-agency-grant,-loan,-and-financial-assistance-programs?utm_source=advisory&utm_medium=email&utm_campaign=2025-01-28_Government_Relations

Summary: The White House Office of Management and Budget (OMB) issued a memorandum (M-25-13) to departments and agencies ordering the temporary pause of all activities – effective 5:00 p.m. on Tuesday, January 28 – related to the obligation or disbursement of all Federal financial assistance to ensure agencies are complying with President Trump's executive orders (EOs) to "ensure that Federal funds are used to support hardworking American families."

Despite a federal judge staying the OMB ordered spending pause until Monday, February 3, numerous questions remain about the original order, particularly if the judge allows the pause to proceed.

While the broad ranging order requires Federal agencies to identify and review all Federal financial assistance programs and supporting activities, it specifically targets programs that "advance Marxist equity, transgenderism, and green new deal social engineering policies" as a "waste of taxpayer dollars."

Learn more about the memorandum's key takeaways and implications, including the potential impact, next steps for agencies, and lawsuits imminent.

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While the broad ranging order requires Federal agencies to identify and review all Federal financial assistance programs and supporting activities, it specifically targets programs that

“advance Marxist equity, transgenderism, and green new deal social engineering policies” as a “waste of taxpayer dollars.” OMB referenced activities that may be implicated – financial assistance for foreign aid, nongovernmental organizations, diversity, equity, and inclusion (DEI), gender ideology, and the green new deal – through the series of EOs issued by the President since his inauguration, including:

Protecting The American People Against Invasion (January 20)

Reevaluating And Realigning United States Foreign Aid (January 20)

Putting America First In International Environmental Agreements (January 20)

Unleashing American Energy (January 20)

Ending Radical And Wasteful Government DEI Programs And Preferencing (January 20)

Defending Women From Gender Ideology Extremism And Restoring Biological Truth To The Federal Government (January 20)

Enforcing the Hyde Amendment (January 24)

The memo does exempt from the temporary freeze payments impacting Medicare or Social Security benefits, as well as other programs providing direct aid to individuals. In addition, OMB may grant exceptions allowing Federal agencies to issue new awards or take other actions on a case-by-case basis.

Potential Impact

The memo noted that of the $10 trillion the Federal Government spent in FY 2024, more than $3 trillion was in the form of Federal financial assistance, grants, and loans. The temporary pause, in essence, could potentially represent a major stoppage in the flow of funds from programs that would be equivalent to about 20 percent of all federal spending – not including interest on the debt – though exemptions could reduce that figure. At the very least, hundreds of billions of dollars in federal grants and loans will be immediately frozen while the White House directive goes into effect and the ramification of the order plays out.

A follow-up OMB guidance clarified that the pause will not affect several specific aid programs, such as Medicaid; Supplemental Nutrition Assistance Program; federal student loans, Pell Grants, Head Start, Section 8 rental assistance, and aid to small businesses and farmers. The guidance indicated that the only funding affected by the freeze would be any grants or loans that run counter to President’s EOs laying out his policies on immigration; abortion; foreign aid;

clean energy; diversity, equity and inclusion programs; and "gender ideology", as well as funding of nongovernmental organizations that undermine the national interest.

Despite the clarification from administration officials, the scope of the 2-page memo remains unclear – leaving much uncertainty into what federal programs could be impacted. Ultimately, which specific federal program gets targeted will be determined not just by each agency, but the White House and political appointees (and perhaps, eventually, by a court of law).

Next Steps for Agencies

As a follow-up to the memorandum temporarily blocking disbursement of grants and loans, OMB issued instructions to agencies for complying with the freeze, which includes instruction sheets asking the federal agencies to inform OMB about all planned obligations and disbursements through March 15. The document asks the agencies, by February 7, to identify a "senior political appointee" responsible for overseeing each program, as well as to identify the estimated date of the next obligation or disbursement of funds.

The follow-up instruction provides a spreadsheet that includes over 2,600 specific accounts within agencies across the government, as well as questions intended to ensure federal programs are in compliance with Trump's executive orders and policy goals. The questions request information relating to, for example, immigration, foreign assistance, climate change, DEI, gender ideology, and the Hyde Amendment (a federal provision prohibiting the use of federal funds to pay for abortion).

The OMB memo pausing disbursements orders agencies to submit, by February 10, information on any programs, projects or activities subject to the freeze. Each agency must pause:

issuance of new awards;

disbursement of Federal funds under all open awards; and

other relevant agency actions that may be implicated by the executive orders, to the extent permissible by law, until OMB has reviewed and provided guidance to the agency with respect to the information submitted.

OMB said that the temporary pause will allow the Administration to review agency programs and determine the best use of funding consistent with the law and the President’s priorities. OMB will likely take a yet to be determined amount of time to review the agency submissions and then

make a decision on what programs to restart and what programs should remain paused – the most likely of the latter will be programs in conflict with the EOs. At this point, OMB will likely seek to indefinitely "defer" certain grants and loans which will result in a court battle to ultimately determine the constitutionality of the Congressional Budget and Impoundment Control Act of 1974 (Public Law 93-344).

Lawsuits Imminent

While the President is generally allowed to defer spending for a period of time if certain conditions are met, the legality of the OMB order will be contested. The Congressional Budget and Impoundment Control Act of 1974 prohibits presidential impoundment of funds appropriated by Congress, as well as various individual appropriations and authorization statutes. The Act establishes procedures the President must follow to propose delaying or rescinding funding.

The follow-up OMB guidance argued that the pause is not an impoundment under the Impoundment Control Act, but rather "a temporary pause to give agencies time to ensure that financial assistance conforms to the policies set out in the President's Executive Orders, to the extent permitted by law."

A group of attorneys general in Democratic-controlled states have announced their intention to file a lawsuit to block the order. Among the states suing include New York, California, Illinois, Massachusetts, New Jersey, and Rhode Island.

In response to the order, Senate Minority Leader Chuck Schumer (D-NY) issued a statement calling on the President to reverse the directive, "Congress approved these investments and they are not optional, they are the law…Donald Trump's Administration is jeopardizing billions upon billions of community grants and financial support that help millions of people across the country. It will mean missed payrolls and rent payments and everything in between: chaos for everything from universities to non-profit charities."

In a letter to Acting OMB Director Matthew Vaeth, House and Senate Appropriations Committee Democratic leaders, Rep. Rosa DeLauro (D-CT) and Sen. Patty Murray (D-WA), warned that the scope of the order is "breathtaking, unprecedented, and will have devastating consequences across the country" and called on the Administration to "uphold the law and the Constitution and ensure federal resources are delivered in accordance with the law."

The memo acknowledged the legal limits of executive power to interfere in legally mandated programs, stating that agencies should carry out the pause "to the extent permissible under applicable law."

Article Title: FDA Reopens Door for Flavored Cigars and Menthol Cigarettes

Category: Life Sciences

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Link: https://www.bipc.com/fda-reopens-door-for-flavored-cigars-and-menthol-cigarettes?&utm_source=advisory&utm_medium=email&utm_campaign=2025-01-24_LifeSciences

Summary: Last week, the U.S. Food and Drug Administration withdrew its proposed rules on flavored cigars along with its rule on menthol cigarettes.

This not only concludes the current rulemaking for both classes of tobacco products, but upends years of proposed rulemaking.

Article:
Last week, the U.S. Food and Drug Administration (FDA) withdrew its proposed rules on flavored cigars along with its rule on menthol cigarettes. This not only concludes the current rulemaking for both classes of tobacco products, but upends years of proposed rulemaking.

On April 29, 2021, FDA announced its intention to advance and adopt two tobacco product standards to ban menthol as a characterizing flavor in cigarettes and ban all characterizing flavors (including menthol) in cigars. Then, on May 4, 2022, FDA published the two proposed tobacco product standard rules in the Federal Register, which received over 225,000 comments prior to ending the comment period on August 2, 2022.

FDA was expected to publish final rules banning menthol cigarettes and flavored cigars in 2023. However, on April 26, 2024, and after much speculation, Xavier Becerra, the Secretary of Health

and Human Services, announced it would take FDA "significantly more time" to finalize the rule on menthol cigarettes with the implication that FDA would also require additional time to promulgate similar rules for flavored cigars.

With these recent withdraws, the rulemakings regarding flavored cigars and menthol cigarettes appear to be dead for the time being. However, FDA is not prevented from changing its mind and reinitiating the rule making process to again attempt to ban these products in the future.

Regardless, these position reversals show that positive change may be coming for the flavored vape products category, which has been under heavy scrutiny by certain state and federal regulators for the past few years. This is particularly true in light of FDA's recent Marketing Granted Orders for nicotine pouch products (which come in flavors such as cinnamon, citrus, mint and wintergreen) and Four Menthol-Flavored E-Cigarette Products.

We will continue to keep you updated as these matters evolve. Please do not hesitate to reach out to the experienced and uniquely qualified FDA and Government Relations teams at Buchanan. We are available to discuss these recent developments and address questions regarding the regulation of tobacco products.

Article Title: What to Expect from the Federal Trade Commission Under Andrew Ferguson's Lead

Category: Antitrust

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Link: https://www.bipc.com/what-to-expect-from-the-federal-trade-commission-under-andrew-ferguson%E2%80%99s-lead?utm_source=advisory&utm_medium=email&utm_campaign=2025-01-28_Litigation

Summary: Every change of Administration brings a change at the Federal Trade Commission (FTC).

Based on past statements, we believe President Trump's appointee for Chair of the FTC, Andrew Ferguson, will lead the FTC in applying a stricter interpretation of antitrust laws, as well as a stricter interpretation of the FTC's authority to enforce those laws. We believe that Commissioner Ferguson will look on a case-by-case basis for clear violations that embrace traditional economic theories of harm.

Learn more about what to expect from this leadership change at the FTC, including background and industry-specific takeaways.

(a) Article:

Summary

Every change of Administration brings a change at the Federal Trade Commission (FTC). The pendulum typically swings slightly back and forth with each change, but for the most part, companies and individuals can expect some consistency in the enforcement of long-established antitrust laws and principles, with changes on the margins. However, former President Biden's appointment of Lina Khan as FTC Commissioner in 2021 led to a broad swing toward heavy enforcement and broad interpretations of the FTC's authority to reign in unfair business practices, protect workers, and advance modern economic theories. It appears President Trumps's appointee — Andrew Ferguson — will swing the pendulum back in the other direction. But, interpreting Ferguson's dissenting statements since he became a Commissioner, and his recent actions, make any prediction difficult. At this point, we believe Ferguson will apply a stricter interpretation of antitrust laws and the FTC's authority to enforce them, looking for clear violations on a case-by-case basis that embrace more traditional economic theories of harm. He will also likely lead a Commission that is more willing to accept fixes and behavioral remedies to problematic mergers and acquisitions.

2. **Background**

Ferguson has been a Commissioner since April 2024, and after his elevation to FTC Chair last week, Ferguson is tasked with leading enforcement of the nation's competition and consumer protection laws. A review of Ferguson's statements while serving as an FTC Commissioner provides insight into how the agency under his leadership will enforce such laws. Ferguson has supported various enforcement actions and objectives, but has been a vocal opponent to the Khan-led FTC in the manner of pursuit of antitrust enforcement, issuing at least 35 dissenting statements both relating to specific cases and general FTC actions.[1] For example, he has challenged several rulemaking decisions, dissenting against the Democratic majority and criticizing the FTC for overstepping its authority. While he has hinted at limiting antitrust enforcement, such as pulling back on the FTC's broad ban on non-compete agreements, Ferguson has expressed his desire to apply pressure on "Big Tech," vowing to end Big Tech's alleged vendetta against competition and free speech.

Ferguson, who is the former Virginia solicitor general and former law clerk for Supreme Court Justice Clarence Thomas, inherits ongoing cases and investigations that target Big Tech, pharmacy benefit managers (PBMs), health insurers, and energy companies. It is unlikely that the new FTC Chair and the FTC will initiate an immediate about-face on specific active cases and investigations. Indeed, commentators contend that a Ferguson-led FTC will maintain an aggressive antitrust enforcement posture, but with different priorities. On the other hand, Ferguson has already taken steps to change the FTC, notably: (1) ending the FTC's diversity, equity and inclusion program; (2) requiring the other Commissioners to quickly vote on a motion to give him the undefined power "'to modify' the previous Commission's strategic plan 'and to take any other action' he deems necessary to comply with [the President's] Executive Orders"[2]; and (3) removing requests for public comment on five requests for information.[3]

3. Industry Specifics

As it relates to **Big Tech**, Ferguson intends to stand up to Big Tech censorship — a view he said was shaped around Big Tech platforms' content moderation concerning COVID-19 and the 2020 election, which included the removal of posts under misinformation rules. Ferguson takes a cautious position, however, with regulation of artificial intelligence (AI). He has criticized the FTC in the past for calling on comprehensive AI legislation, noting that a regulatory response is too soon in the early stages of AI development. He also criticized the FTC for referring a complaint related to Snap, Inc.'s use of AI to the Department of Justice, claiming "the complaint's application of Section 5 of the Federal Trade Commission Act is not only wrong as a matter of statutory interpretation, but is also in direct conflict with the guarantees of the First Amendment."[4] On January 17, 2025, Ferguson issued a concurring and dissenting statement to the Khan-led FTC's Staff Report on AI Partnerships & Investments 6(b) Study, insisting on a balanced approach to analyzing AI's effects on competition by stating:

On the one hand, the Commission must not charge headlong to regulate AI. Such regulation could strangle this nascent technology in its cradle, or move the development of the technology to foreign states hostile to our national interests. On the other hand, the Commission must remain a vigilant competition watchman, ensuring that Big Tech incumbents do not control AI innovators in order to blunt any potential competitive threats.[5]

PBMs and health insurers will likely face continued scrutiny from the incoming FTC Chair. President Trump has publicly voiced his discontent with PBMs, signaling they will remain a focus of the FTC given Ferguson's position that he is bound to follow the President's orders.[6] In addition, Ferguson has provided cautious support to the FTC's reports on PBMs. In September 2024, the FTC sued the largest PBMs, accusing them of engaging in illegal rebate programs that drove up the price of insulin.[7] The FTC most likely will continue investigating PBM practices as rising healthcare costs and quality of care are a bipartisan issues. On January 14, 2025, Ferguson issued a concurring statement on the FTC's Second PBM Interim Staff Report, indicating that the FTC "still has more work to do on this Section 6(b) study. I remain committed to bringing it to a conclusion, culminating in a final report."[8] He also supported the study generally with a concurring statement for the First Interim Staff Report.[9]

The energy industry may be the first to see a return to more traditional levels of antitrust scrutiny of mergers in comparison to the increased scrutiny under Khan's lead. Prior to Khan's time as Chair, the FTC seldom challenged horizontal mergers of energy companies considering the companies operate in global markets. Under Khan's lead, however, the FTC advanced expansive theories of harm, including allegations that a merger would violate Section 7 because the former CEO of the target company, who had previously made public statements inviting competitors to restrict output, would have become a Board member of the acquiring company. Ferguson issued a dissenting statement arguing that there was no evidence that the transaction itself violated Section 7 of the Clayton Act by substantially lessening competition, notwithstanding the potential anticompetitive suggestions of the former CEO. That being said, transactions for which evidence exists indicating effects on consumer energy prices under traditional theories of harm will likely face intense scrutiny given the bipartisan focus on cutting energy costs for consumers.

4. Conclusion

Ultimately, Ferguson recognizes the FTC's "traditional role as a cop on the beat,"[10] that will enforce the laws passed by Congress. In all likelihood, he will not advance an aggressive rulemaking stance. For example, Ferguson dissented from the FTC's nationwide ban on noncompete agreements, arguing that the FTC lacked clear authority from Congress for such a ban. The rule has been blocked by a federal district court and is currently on appeal, but Ferguson's opposition suggests the FTC will not provide further support. Ferguson also has criticized various actions taken by the Khan-led FTC "on their way out the door" and suggested that, under his lead, the FTC will take corrective action. For example, on January 16, 2025, the FTC approved changes to its rule implementing the Children's Online Privacy Protection Act. Ferguson issued a concurring statement explaining his belief of three problems with the rule, saying: "No one should have any doubt that these issues are the result of the Biden-Harris FTC's frantic rush to finalize rules on their way out the door. The Commission under President Trump should address these issues and fix the mess that the outgoing majority leaves in its wake." If there were any doubt the Ferguson plans to make his own mark, in his dissenting statement to the FTC and Department of Justice's release of Antitrust Guidelines for Business Activities Affecting Workers, he concluded: "The Biden-Harris FTC has no future."[11]

While the new-look FTC may be friendlier to mergers and acquisitions in the sense that they will pursue traditional theories, be open to fixes or behavioral remedies, and not push the boundaries of antitrust and economics, bipartisan concerns in Big Tech, healthcare, and energy means that antitrust compliance will remain paramount for companies at least in those sectors. All industries should watch this FTC closely and be ready to pivot. Buchanan's antitrust team is available to assist companies in navigating the new-look FTC.

1. https://www.ftc.gov/about-ftc/biographies/andrew-n-ferguson/speeches-articles-testimonies?page=0

2. Statement of Rebecca Slaughter: /https://www.ftc.gov/system/files/ftc_gov/pdf/2025-1-23_rks_statement_motion_delegation.pdf

3. Requests for Public Comment allow the FTC to gather information from the public on issues that may be of importance to individuals and businesses. See Request for Public Comments Regarding Protecting Workers from Illegal Business Practices - https://www.regulations.gov/docket/FTC-2025-0008; Request for Public Comments Regarding Small Businesses, Entrepreneurs, and Start-Ups - https://www.regulations.gov/docket/FTC-2025-0010; Request for Public Comments Regarding Mergers and Acquisitions - https://www.regulations.gov/docket/FTC-2025-0009; Request for Public Comments Regarding Predatory Pricing - https://www.regulations.gov/docket/FTC-2025-0011; Request for Public Comments Regarding Surveillance Pricing Practices - https://www.regulations.gov/docket/FTC-2025-0007

4. https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-snap-statement.pdf

5. https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-ai-6b-statement.pdf

6. https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-dei-delegation-statement.pdf

7. Commissioner Ferguson recused himself from the vote on the complaint and did not issue any statement. https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices

8. https://www.ftc.gov/system/files/ftc_gov/pdf/pbm-6b-second-interim-staff-report-ferguson-concurrence-final.pdf

9. https://www.ftc.gov/system/files/ftc_gov/pdf/Ferguson-Statement-Pharmacy-Benefit-Managers-Report.pdf

10. https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-dissent-2024-annual-regulatory-plan-agenda.pdf

11. https://www.ftc.gov/system/files/ftc_gov/pdf/at-guidelines-for-business-activities-affecting-workers-ferguson-holyoak-dissent.pdf

Article Title: Amendments to International Trade Commission's Amendment to Rules of Practice and Procedure

Category: International Trade & National Security

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Link: https://www.bipc.com/amendments-to-international-trade-commission%E2%80%99s-amendment-to-rules-of-practice-and-procedure?utm_source=advisory&utm_medium=email&utm_campaign=2024-01-29_International_Trade

Summary: On February 3, 2025, amendments to the International Trade Commission's (Commission) Rules of Practice and Procedure are scheduled to take effect.

The amendments focus on revising procedures and rules of general application, safeguards, antidumping and countervailing duty (AD/CVD) investigations, and section 337 adjudication and enforcement.

Learn more about these amendments, including takeaways for companies involved in international commerce.

Article:
On February 3, 2025, amendments to the International Trade Commission's (Commission) Rules of Practice and Procedure are scheduled to take effect.[1] The Commission announced the forthcoming amendments on January 3, 2025, following a period of notice-and-comment.[2] The rule adopts, with minor exceptions, the amendments proposed by the Commission on March 28, 2024.[3]

The amendments focus on revising procedures and rules of general application, safeguards, antidumping and countervailing duty (AD/CVD) investigations, and section 337 adjudication and enforcement.[4] The Commission described the amendments as "necessary to make certain technical corrections, to clarify certain provisions, to harmonize different parts of the Commission's rules, and to address concerns that have arisen in Commission practice."[5]

At a high level, many of the Commission's amendments for general practice and AD/CVD proceedings are technical in nature: such as corrections of typographical errors, adoption of gender-neutral language, the establishment of permanent electronic filing procedures in lieu of or as an alternative to paper copies, and allowing witness testimony to be filed the day of hearings.[6] Additionally, the Commission's amendments clarify the requirements for the content and filing of complaints with the Commission and align certain discovery rules with the Federal Rules of Civil Procedure.[7]

Buchanan's International Trade and National Security Group is currently monitoring the potential impact on the scheduled effective date of the Commission's amendments due to the Executive Order issued by President Trump on January 20, 2025.

1. *Practice and Procedure: Rules of General Application, Safeguards, Antidumping and Countervailing Duty Investigations, and Section 337 Adjudication and Enforcement*, 90 Fed. Reg. 225 (Jan. 3, 2025) (*Practice and Procedure*). On January 21, 2025, President Trump issued an executive order requesting that all executive departments and agencies consider postponing the effective date for any rules published in the Federal Register or rules which have not yet taken effect for 60 days. *Regulatory Freeze Pending Review*, (Jan. 20, 2025), https://www.whitehouse.gov/presidential-actions/2025/01/regulatory-freeze-pending-review/.

2. *Practice and Procedure*, 90 Fed. Reg. at 225.

3. *Practice and Procedure: Rules of General Application, Safeguards, Antidumping and Countervailing Duty Investigations, and Section 337 Adjudication and Enforcement*, 89 Fed. Reg. 22,012 (Mar. 28, 2024).

4. The Commission proposed amendments to its rules governing proceedings conducted under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), as well as Title VII of the Tariff Act of 1930, which comprises 19 U.S.C. 1671-1677n, sections 201-202, 204, and 406 of the Trade Act of 1974 (19 U.S.C. 2251-2252, 2254, and 2436), and sections 301-302 of the United States-Mexico-Canada Implementation Act (19 U.S.C. 4551-4552). *See Practice and Procedure*, 90 Fed. Reg. 225.

5. *Id.*

6. *See* Practice and Procedure, 90 Fed. Reg. at 226-32. A complete summary of the proposed amendments is included in the January 3rd final rule.

7. *Id*.

Article Title: Eleventh Circuit Invalidates FCC's Attempt to Alter Meaning of Prior Express Written Consent

Category: Litigation

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Link: https://www.bipc.com/eleventh-circuit-invalidates-fcc%E2%80%99s-attempt-to-alter-meaning-of-prior-express-written-consent?utm_source=advisory&utm_medium=email&utm_campaign=2025-01-29_Litigation

Summary: In 2023, the FCC issued a legislative rule interpreting the meaning of the phrase "prior express consent" as used in the TCPA.

On January 24, 2025, the Eleventh Circuit found that the proposed rule was invalid and held that the FCC exceeded its statutory authority under the TCPA when it enacted the proposed rule because its new consent restrictions "impermissibly conflict with the ordinary statutory meaning of "prior express consent."

Learn more about takeaways for companies regarding this ruling, including its impact on the one-to-one-consent restriction and the logically-and-topically related restriction.

Article:
In 2023, the FCC issued a legislative rule interpreting the meaning of the phrase "prior express consent" as used in the TCPA. The proposed rule sought to close the "lead generator loophole," and would impose new consent requirements on telemarketers. First, it would require both "one-to-one" consent, meaning telemarketers must individually obtain "prior express written consent" from consumers for *each* entity attempting to make robocalls to those consumers. Second, it would require that the robocalls consented to were logically and topically associated with the interaction that prompted the consent. In other words, telemarketers could not obtain "prior express written consent" to make robocalls to consumers using their milk sales website to also make robocalls to that consumer about cookies.

On January 24, 2025, the Eleventh Circuit found that the proposed rule was invalid and held that the FCC exceeded its statutory authority under the TCPA when it enacted the proposed rule because its new consent restrictions "impermissibly conflict with the ordinary statutory meaning of "prior express consent."

5. The One-to-One-Consent Restriction

In rejecting the one-to-one-consent restriction, the Eleventh Circuit noted the breadth of "prior express consent" under the TCPA, highlighting both in-circuit and out-of-circuit cases in which called parties were found to have given prior express consent to multiple entities at one time. *Id.* at 18.[1] Further, the Eleventh Circuit noted that the FCC itself acknowledged in its briefing that a consumer could give "prior written consent" under the TCPA to receive robocalls from multiple entities without consenting separately to each caller, but that such consent would not satisfy the 2023 Order's one-to-one-consent restriction. Order at 19. Though the FCC argued that a

consumer should not be presumed to have willingly consented to receive robocalls from more than one entity at a time, the Eleventh Circuit found that the restriction exceeded the FCC's statutory authority to "implement" the TCPA. *Id*. at 18. The court also concluded that, despite the FCC's argument that the 2023 Order was "good policy," "atextual policy cannot overcome clear text." *Id*. at 20.

6. **The Logically-and-Topically Related Restriction**

The Eleventh Circuit next tackled the "logically-and-topically related restriction," finding that, like the one-to-one consent restriction, it also impermissibly altered the meaning of "prior express consent." *Id*. at 21. The court noted that a consumer shopping online for auto loans on an auto loan website could check a box consenting to calls from a bank about auto loans and, additionally, check a box consenting to calls from that same bank about loan consolidation and, under the 2023 Order, the consent to receive calls about loan consolidation would be invalid. *Id*. at 21-22. Why? Because the consumer was not on a loan consolidation website—they were on an auto loan website. Under the TCPA, however, a consumer has given "prior express consent" when they clearly and unmistakably state, prior to receiving a robocall, that they are willing to receive the robocall.[2] Ultimately, the Eleventh Circuit found that, "[j]ust like the one-to-one consent restriction . . . this restriction impermissibly alters what it means to give "prior express written consent." *Id*. at 21.

In its attempt to "implement" the TCPA, the FCC overstepped statutory boundaries. "Agencies have only those powers given to them by Congress, and 'enabling legislation' is generally not an 'open book to which the agency [may] add pages and change the plot line.'" But changing the plot line is exactly what the FCC tried to do here. "Congress drew a line in the text of the statute" between "prior express consent" and something more burdensome. Rather than respecting the line that Congress drew, the FCC stepped right over it.

Id. at 26.

If a TCPA case has been filed against your company, consider whether the regulations the plaintiff has invoked fit within the plain language of the TCPA and the FCC's statutory authority to *implement*, rather than alter, the statute's plain language. Buchanan Ingersoll & Rooney PC attorneys have vast experience litigating TCPA claims, as well as claims brought under the TCPA's state law equivalents, including the Florida Telephone Solicitation Act. Buchanan attorneys also work with companies to optimize their telemarketing policies for compliance with TCPA and its state law equivalents.

1. *See Gorss Motels, Inc. v. Safemark Sys.,* LP, 931 F.3d 1094, 1100-02 (11th Cir. 2019)(fax recipients gave "prior express permission" to receive faxed advertisements by agreeing in a single franchise agreement to receive faxes from a both a specific hotel and its affiliates); *Mais v. Gulf Coast Collection Bureau*, 768 F.3d 1110, 1124–25 (11th Cir. 2014) (finding prior express consent where the plaintiff's wife consented to robocalls from more than one entity at a time); *Lucoff v. Navient Sols., LLC*, 981 F.3d 1299, 1306 (11th Cir. 2020) (finding prior express consent where the plaintiff agreed to receive calls from multiple entities); *Fober v. Mgmt. & Tech. Consultants, LLC*, 886 F.3d 789, 791,

793–94 (9th Cir. 2018) (similar); *Baisden v. Credit Adjustments, Inc.*, 813 F.3d 338, 346–47 (6th Cir. 2016) (similar).

2. *See Gorss Motels*, 931 F.3d at 1100; *Schweitzer*, 866 F.3d at 1279.

Article Title: Securities and Exchange Commission Crypto Asset Developments

Category: Blockchain & Digital Assets

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Link: https://www.bipc.com/securities-and-exchange-commission-crypto-asset-developments?utm_source=advisory&utm_medium=email&utm_campaign=2025-1-30_Tax

Summary: On January 21, 2025, the Securities and Exchange Commission's Acting Chairman announced the launch of a crypto task force to develop a "comprehensive and clear regulatory framework" for crypto assets.

The Task Force's main goal is to establish a regulatory framework that promotes innovation while protecting investors. This is important because the Securities and Exchange Commission has primarily relied on enforcement actions and ad hoc interpretations to regulate cryptocurrencies, resulting in confusion and hindering progress.

By creating clear regulations, the Task Force aims to enhance the integrity and value of the underlying technology.

Article:
On January 21, 2025, the Securities and Exchange Commission's Acting Chairman Mark T. Uyeda announced the launch of a crypto task force (the Task Force) to develop a "comprehensive and clear regulatory framework" for crypto assets. The Task Force will be led by Commissioner Hester Pierce, and assisted by Richard Gabbert, Senior Advisor to the Acting Chairman, and Taylor Asher, Senior Policy Advisor to the Acting Chairman, who will serve as the Task Force's Chief of Staff and Chief Policy Advisor, respectively. The Task Force will be staffed by current

employees across the agency and will collaborate with the Commission's staff as well as with the public.

The core purpose of the Task Force is to develop a sound regulatory framework that would support innovation while ensuring investor safeguards. This is significant because, to date, the Securities and Exchange Commission's regulation of cryptocurrencies, generally, has been through its enforcement actions and *ad hoc* interpretations of the law, which has led to confusion, setbacks in advancement and overall negativity in the integrity of the underlying technology and its value. The Task Force's main purpose is to develop clear and transparent rulemaking that would assist with registration and disclosure requirements for crypto assets as well as promote a friendly environment to support innovation and technological advancements. The use of enforcement actions will be carefully reviewed.

The Task Force will work closely with Congress and operate within the statutory framework provided by Congress. To that end, it will coordinate with other federal departments and agencies, including the Commodity Futures Trading Commission (CFTC), as well as state and international counterparts.

Additionally, on January 23, 2025, the SEC rescinded Staff Accounting Bulletin No. 121 (SAB No. 121), addressing accounting requirements for cryptocurrency companies or those holding crypto assets.

The SEC issued SAB 121 in March 2021, providing guidance on how public companies should account for crypto assets held by them in custodial arrangements (for example, when exchanges like Coinbase or Binance hold cryptocurrencies on behalf of customers).

The guidance aimed to provide accounting for crypto custodianship and disclosure requirements, outside general accounting standards (ergo, Generally Accepted Accounting Principles).

The SEC's rationale to rescind or withdraw SAB 121 indicates a significant shift in its stance on the accounting treatment of crypto assets held by custodians. The Trump Administration's bullish policy on crypto assets with the onboarding of a SEC Task Force signals changing views on crypto and custody, as well as a broader industry impact.

With the rescinding of SAB 121, companies that previously followed its guidelines will likely need to revisit their financial statements and disclosures related to digital assets held for its customers. While there is no immediate new guidance for companies, the SEC has suggested that it will work closely with the Financial Accounting Standards Board (FASB) and other regulatory bodies to develop a consistent framework for crypto assets.

For crypto exchanges and custodians that deal with client funds, the rescindment of SAB 121 means they will have to consider how to account for crypto assets in their balance sheets without the previous staff guidance. This could include: (i) changes in reporting, (ii) more risk disclosures, and (iii) potential impact on valuations.

The SEC's decision to rescind SAB 121 reflects its evolving approach to the accounting treatment of crypto assets, signaling that the regulatory environment is still developing. While crypto companies must now navigate a period of uncertainty regarding how to account for

customer-held crypto assets, this change may eventually lead to clearer and more standardized accounting practices.

The SEC's action is part of a larger trend of increased regulation and oversight in the cryptocurrency space, as regulators continue to grapple with how to balance innovation with investor protection and financial stability.

Article Title: The 2024 EPA PFAS Regulations, EPA PFAS Enforcement Priorities, and Reopener Risks

Category: Environmental

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Link: https://www.bipc.com/the-2024-epa-pfas-regulations,-epa-pfas-enforcement-priorities,-and-reopener-risks?utm_source=advisory&utm_medium=email&utm_campaign=2025-01-31_Environmental

Summary: Several key developments in federal environmental regulation in 2024 were the designation of two PFAS compounds as hazardous substances by the U.S. Environmental Protection Agency (EPA) and the establishment of the first legally enforceable drinking water standards for several PFAS compounds, both individually and in mixtures.

While President Trump's administration may revise the April 2024 PFAS Enforcement Policy, it is unlikely that the basic principles that underlie it, which include focusing on entities that have manufactured and released PFAS, will significantly change.

Learn more about the EPA's enforcement priorities as indicated in an April 2024 EPA PFAS Enforcement Discretion and Settlement Policy and the reopener risk that parties to judicial consent decrees at CERCLA sites may face if EPA aggressively pursues PFAS enforcement through the use of reopener provisions.

Article:
Several key developments in federal environmental regulation in 2024 were the designation of two PFAS compounds as hazardous substances by the U.S. Environmental Protection Agency

(hereinafter EPA) and the establishment of the first legally enforceable drinking water standards for several PFAS compounds, both individually and in mixtures.[1] With the new PFAS hazardous substances regulations in place, parties to EPA consent decrees should examine the potential use of generally included reopener provisions that may allow the EPA to require further PFAS testing and remediation at previously closed superfund sites undergoing the agency's five-year review process.

Lee Zeldin was appointed by President Trump to be the EPA Administrator and recently received Senate confirmation. Although some think tanks have recommended policy priorities for the EPA that include revising "groundwater cleanup regulations and policies to reflect the challenges of omnipresent contaminants like PFAS" and revisiting "the designation of PFAS chemicals as 'hazardous substances' under CERCLA", it is far from clear that the second Trump administration will pursue a reversal of the PFAS regulations put in place by the Biden administration in 2024.[2] Indeed, Mr. Zeldin, during his service in the U.S. House of Representatives, supported legislation that never became law regulating PFAS in drinking water.[3] In addition, President Trump's first administration pursued PFAS regulation to a different degree than the Biden administration yet nevertheless held itself out as "aggressively addressing per- and polyfluoroalkyl substances (PFAS)" as an "active and ongoing priority" of the EPA.[4] In accordance with President Trump's January 20, 2025 Executive Order issuing a regulatory freeze, the Trump administration withdrew an EPA rule that was under review and set forth proposed limits on PFAS in wastewater.[5] The full extent of the Trump administration's policies on PFAS will become apparent as the new administration continues to take shape.

This legal update provides insight into EPA's enforcement priorities as indicated in an April 2024 EPA PFAS Enforcement Discretion and Settlement Policy (hereinafter "EPA PFAS Enforcement Policy") and explains the reopener risk that parties to judicial consent decrees at CERCLA sites may face if EPA aggressively pursues PFAS enforcement through the use of reopener provisions. While President Trump's administration may revise the April 2024 PFAS Enforcement Policy, it is unlikely that the basic principles that underlie it, which include focusing on entities that have manufactured and released PFAS, will significantly change.

7. Designation of PFAS Substances as Hazardous Substances and EPA's Enforcement Policy

Effective July 8, 2024, EPA expanded the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) list of hazardous substances to include two per- and polyfluoroalkyl substances, which are collectively referred to herein as PFAS.[6] In the relevant final rule, the EPA acknowledged that "[p]otential liability for response costs for addressing PFOA and PFOS releases or threatened releases is an indirect effect . . ." of the rule.[7] In addition, in April 2024, the EPA announced the final National Primary Drinking Water Regulation addressing specified PFAS.[8] There is currently pending litigation in the United States Court of Appeals for the District of Columbia Circuit seeking review of the EPA PFAS final rule and the EPA National Primary Drinking Water Regulation.[9]

PFAS, known colloquially as "forever chemicals," have gained significant attention in recent years due to their environmental persistence. The molecules that make up the PFAS group of chemicals are extremely stable and resist naturally occurring degradation in the environment.

Further, they are small enough to pass through most environmental and biological membranes. Since PFAS are found in many cleaning products, non-stick cookware, cosmetics and other consumer goods, PFAS chemicals have accumulated within waste sites.[10]

The designation of PFAS as a hazardous substance allows the EPA to use the full strength of its authority under CERCLA to address PFAS contamination. CERCLA provides the EPA with authority to compel investigations and cleanups of sites contaminated by certain hazardous substances. CERCLA also allows potentially responsible parties (PRPs) to negotiate with the EPA to enter into either administrative settlements or judicial consent decree settlements. Through consent decrees, landowners, generators, and transporters may be released from liability in exchange for financial contributions.

EPA has broad enforcement and settlement discretion under CERCLA. Pursuant to its PFAS Enforcement Policy, the EPA intends to ". . . focus on holding accountable those parties that have played a significant role in releasing or exacerbating the spread of PFAS into the environment, such as those who have manufactured PFAS or used PFAS in the manufacturing process, and other industrial parties."[11] Those parties are referred to as major PRPs.[12] EPA also intends to pursue federal agencies and federal facilities that are responsible for PFAS contamination.[13] EPA indicated that, in settlements with such parties, it will seek to require the settling parties to waive their rights to sue non-settling parties that satisfy certain equitable requirements.[14]

EPA also does not currently intend to pursue, based on equitable factors, the following PRPs: community water systems and POTWs (publicly owned treatment works), municipal separate storm sewer systems (MS4s), publicly owned or operated municipal solid waste landfills, publicly owned airports and local fire departments, and farms that apply biosolids to lands.[15] EPA also stated that it will exercise its discretion and consider fairness and other equitable factors when deciding whether to pursue PFAS actions based on a number of criteria, including whether the entity performs a public service role in activities that include, for example, the handling of municipal solid waste and treating or managing stormwater or wastewater.[16] An aspect of EPA action to monitor is how a "public service role" is defined when the EPA applies its enforcement discretion with regard to municipal solid waste treatment.

8. Reopener Liability Under CERCLA as a Result of PFAS Regulations

It is notable that the EPA's settlement authority, exercised through the entry of consent decrees, features prominently in the EPA PFAS Enforcement Policy. Importantly, federal RD/RA judicial consent decrees in accordance with Section 122(f)(6) of CERCLA include "reopener provisions."[17] These provisions allow the EPA, under specific circumstances, to retroactively reopen and renegotiate a consent decree to supplement a previous settlement with additional obligations. It is anticipated that such reopener provisions may be invoked, at the EPA's discretion, in the implementation of the new PFAS regulations.

EPA provides a Model RD/RA Judicial Consent Decree as a template for negotiation, and the model consent decree includes the following reopener provision:

Notwithstanding any other provision of this Decree, the United States reserves, and this Decree is without prejudice to, the right to issue an administrative order or to institute proceedings in this action or in a new action seeking to compel Settling Defendants . . . to perform further response action to the Site, to pay the United States for additional costs of response, or any combination thereof. The United States may bring a claim under this reservation only if, at any time, conditions at the Site previously unknown to EPA are discovered, or information previously unknown to EPA is received, and EPA determines, based in whole or in part on these previously unknown conditions or information, that the Remedial Action is not protective of public health or welfare or the environment.[18]

Under Section 122(g)(1)(A) of CERCLA, the EPA may enter into settlement agreements with certain *de minimis* parties for which more expeditious settlements may be reached because only a minor portion of the response costs at the facility are involved and certain specified conditions are met.[19] Covenants not to sue may be included in *de minimis* settlements, and the EPA will typically include reopeners in such settlements,[20] examples of which can be found in the model *de minimis* consent decree. An excerpt of one reopener provision in the model *de minimis* consent decree is as follows:

Notwithstanding any other provision in this Consent Decree, the United States reserves, and this Consent Decree is without prejudice to, the right to institute proceedings against any individual Settling Defendant in this action or in a new action or to issue an administrative order to any individual Settling Defendant seeking to compel that Settling Defendant . . . to perform response actions relating to the Site, and/or to reimburse the United States for additional costs of response, if: information is discovered that indicates that such Settling Defendant . . . contributed hazardous substances to the Site in such greater amount or of such greater toxic or other hazardous effects that such Settling Defendant . . . no longer qualifies as a *de minimis* party at the Site because [**insert volume and toxicity criteria from Section I, Paragraph C.3, e.g.:** Settling Defendant . . . . contributed greater than ___% of the hazardous substances at the Site, or contributed hazardous substances that are significantly more toxic or are of significantly greater hazardous effect than other hazardous substances at the Site].[21]

While this reopener is differently configured than the reopener typically included in the Model RD/RA Judicial Consent Decree, it could be triggered by a *de minimis* party's PFAS contributions that were not taken into consideration at the time the party qualified as a *de minimis* party. In addition to this reopener, *de minimis* consent decrees must include a reopener that "claims for natural resource damages will be 'expressly reserved unless the Federal natural resource trustee has agreed in writing' to the settlement"[22] and may also contain a reopener related to a situation in which the total cost incurred or to be incurred at a site exceeds a certain threshold.[23]

Many federal consent decrees are reviewed by the EPA on a five-year basis, providing an opportunity for the EPA to realize the need to reopen a consent decree and require additional remediation.[24] Should a consent decree be reopened, the PRP may ultimately have additional liability and increased financial obligations that would be imposed long after the initial settlement. In summary, reopeners are used as tools for the EPA to confront cleanup demands that may arise from unknown site conditions, ineffective remediation methods, or future

scientific advancements and therefore may be used by the EPA with regard to the designation of PFAS as a hazardous substance.

9. PFAS and the Risk of Reopener Liability

Considering the ubiquity of PFAS in many different types of products and industrial usages, the designation of certain PFAS as hazardous substances raises the possibility of reopening existing consent decrees in order to address PFAS contamination. As enforcement of the EPA PFAS regulation expands, the EPA's use of reopener provisions may begin to be observed more frequently in enforcement trends.[25] In 2025, the EPA is set to conduct approximately 100 five-year reviews, providing ample opportunity for trends in reopener liability to become apparent.[26]

As the 2024 PFAS regulations combined with the possibility of reopener liability and five-year reviews demonstrate, consent decrees with the federal government settle important issues yet most consent decrees remain open to revision for further remediation requirements when a hazardous substance present at a previously closed superfund site is officially designed through EPA rulemaking.

Indeed, the reopener issue is relevant to sites even where the site has not been "closed." Many sites are in a groundwater monitoring phase and thus still active. The PFAS issue would present the same issues to the PRPs at those sites.

Buchanan's environmental and energy attorneys are prepared to proactively assist clients in evaluating consent decrees to ensure that they understand the reopener risk associated with the EPA's potential enforcement of the 2024 PFAS regulations.

1. The EPA also took other actions on PFAS that are summarized on the following website: Key EPA Actions to Address PFAS, https://www.epa.gov/pfas/key-epa-actions-address-pfas (last accessed Jan. 16, 2025).

2. Mandy M. Gunasekara, *Environmental Protection Agency,* in The Heritage Foundation, Mandate for Leadership: the Conservative Promise – Project 2025, 431 (Paul Dans and Seven Groves, eds. 2023).

3. Bobby Magill, *Trump Era Pick Seen Supporting PFAS Limits, Revising Water Rules*, Bloomberg Law News, Nov. 13, 2024.

4. U.S. Env't Prot. Agency, Trump EPA Continues to Aggressively Address PFAS on the Federal, State, and Local Level (July 28, 2020), https://www.epa.gov/newsreleases/trump-epa-continues-aggressively-address-pfas-federal-state-and-local-level.

5. *See* Ass'n of State Drinking Water Adm'r, *OMB Withdraws EPA's PFAS Effluent Limitation Guidelines and Standards Proposed Rule*, https://www.asdwa.org/2025/01/24/omb-withdraws-epas-pfas-effluent-limitation-guidelines-and-standards-proposed-rule/ (last accessed Jan. 26, 2025); Executive Order on Regulatory Freeze Pending Review of President Donald J. Trump (Jan. 20,

2025), https://www.whitehouse.gov/presidential-actions/2025/01/regulatory-freeze-pending-review/ (last accessed Jan. 26, 2025).

6. Hazardous Substances And Reportable Quantities, 40 C.F.R. § 302.4 (2024). The substances designated by this rule include perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). *See Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances*, 89 Fed. Reg. 39,124 (EPA May 8, 2024).

7. *See Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances*, 89 Fed. Reg. 39,124, 39,128 (EPA May 8, 2024).

8. *See* 40 C.F.R. §§ 141, 142. *See also:* PFAS National Primary Drinking Water Regulation, 89 Fed. Reg. 32,532 (EPA April 26, 2024); PFAS National Primary Drinking Water Regulation, Correction, 89 Fed. Reg. 49,101 (EPA June 11, 2024).

9. *Chamber of Com. of the U.S. et. al., v. EPA et. al.,* No. 24-1193 consolidated with Nos. 24-1261, 24-1266-24-1271, and 24-1272 (D.C. Cir.) (seeking review and challenging the EPA's final rule designating PFAS as a hazardous substance); *American Water Works et. al. v. EPA et. al*., No. 24-1188 consolidated with Nos. 24-1191 and 24-1192 (D.C. Cir) (seeking review and challenging the EPA's final rule entitled "PFAS National Primary Drinking Water Regulation").

10. U.S. Env't Prot. Agency, Our Current Understanding of the Human Health and Environmental Risks of PFAS, https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas.

11. U.S. Env't Prot. Agency, PFAS Enforcement and Discretion and Settlement Policy under (CERCLA), 2-3 (April 19, 2024), *https://www.epa.gov/enforcement/pfas-enforcement-discretion-and-settlement-policy-under-cercla*.

12. *Id.* at 3.

13. *Id.*

14. *Id.*

15. *Id.* at 6-8.

16. *Id.* at 8. The full list of factors considered for enforcement discretion is as follows: "[w]hether the entity is a state, local, or Tribal government, or works on behalf of or conducts a service that would otherwise be performed by a state, local, or Tribal government", whether the entity performs specified public service roles, "[w]hether the entity has manufactured PFAS or used PFAS as part of an industrial process", and "[w]hether, and to what degree, the entity is actively involved in the use, storage, treatment, transport, or disposal of PFAS."

17. *See* 42 U.S.C. § 9622(f)(6)(a) (providing "[e]xcept for the portion of the remedial action which is subject to a covenant not to sue under paragraph (2) or under subsection (g) (relating to de minimis settlements), a covenant not to sue a person concerning future liability to the United States shall include an exception to the covenant that allows the President to sue such person concerning future liability resulting from the release or threatened release that is the subject of the covenant where such liability arises out of conditions which are unknown at the time the President certifies under paragraph (3) that remedial action has been completed at the facility concerned.");

18. *See* U.S. Env't Prot. Agency: Model Remedial Design/Remedial Action Consent Decree, 508 Compliant Version, July 2024 at ¶ 71(a), https://cfpub.epa.gov/compliance/models/view.cfm?model_ID=81.

19. *See* 42 U.S.C. § 9622(g)(1)(A)-(B) (indicating that *de minimis* settlements can be reached if "(A) Both of the following are minimal in comparison to other hazardous substances at the facility: (i) The amount of the hazardous substances contributed by that party to the facility," and "(ii) The toxic or other hazardous effects of the substances contributed by that party to the facility"or if "(B) The potentially responsible party - (i) is the owner of the real property on or in which the facility is located; (ii) did not conduct or permit the generation, transportation, storage, treatment, or disposal of any hazardous substance at the facility; and (iii) did not contribute to the release or threat of release of a hazardous substance at the facility through any action or omission." In addition, "[t]his subparagraph (B) does not apply if the potentially responsible party purchased the real property with actual or constructive knowledge that the property was used for the generation, transportation, storage, treatment, or disposal of any hazardous substance.")

20. Peter L. Gray, The Superfund Manual: A Practitioner's Guide To CERCLA Litigation 182 (American Bar Association 2016).

21. *See* U.S. Environmental Protection Agency: Model Consent Decree Section 122(g)(4) *de minimis* contributor consent decree, March 2023 at § IX, ¶ 16(a).

22. Gray, *supra* note 20 at 182.

23. *See* U.S. Environmental Protection Agency: Model Consent Decree Section 122(g)(4) *de minimis* contributor consent decree, March 2023 at § IX, ¶ 16(b).

24. *See* 42 U.S.C. § 9621(c) (providing that "[i]f the President selects a remedial action that results in any hazardous substances, pollutants, or contaminants remaining at the site, the President shall review such remedial action no less often than each 5 years after the initiation of such remedial action to assure that human health and the environment are being protected by the remedial action being implemented."); *see also* 40 C.F.R. § 300.430(f)(4)(2) (indicating that "[i]f a remedial action is selected that results in hazardous substances, pollutants, or contaminants remaining at the site above levels that allow for unlimited use and unrestricted exposure, the lead agency shall review such action no less often than every five years after initiation of the selected remedial action.")

25. Although this analysis focused on the federal PFAS regulations, states have diverse PFAS regulations, which could potentially result in reopeners of consent decrees or other settlement agreements on the state level.

26. Jeffrey Talbert, *Are Superfund Sites Ever Really Closed?*, N.Y. L.J., Oct. 30, 2024.

Article Title: Navigating the Next Wave of Privacy Claims: How to Avoid Becoming a 'Web Wiretapping' Target

Category: Cybersecurity & Data Privacy

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Link: https://www.bipc.com/navigating-the-next-wave-of-privacy-claims-how-to-avoid-becoming-a-web-wiretapping-target?utm_source=advisory&utm_medium=email&utm_campaign=2024-12-20_Cybersecurity

Summary: In addition to developments in chat, pixel, pen register, trap and trace, and search bar pixel cases, other website privacy claims are emerging and becoming more prevalent in several states.

These include allegations that common email marketing analytics technologies may violate the Arizona Telephone, Utility and Communication Service Records Act and privacy claims under the Song-Beverly Credit Card Act.

To avoid potential claims, we recommend key strategies to assess and adapt your data privacy policies and compliance efforts.

Article:
In previous posts, we examined the rise of chat and pixel cases under Section 631(a) of the California Invasion of Privacy Act (CIPA), as well as the increasing prevalence of pen register, trap and trace cases, and search bar pixel cases under CIPA Section 638.51. In this post, we

discuss other trending privacy claims and offer recommendations to help you avoid becoming a target of website-based privacy lawsuits and arbitration claims.

Alongside these developments, other website privacy claims are evolving and becoming increasingly prevalent in several states. For instance, cases alleging that common email marketing analytics technologies can violate the Arizona Telephone, Utility and Communication Service Records Act (Arizona Act) are on the rise. Major retail companies such as Target[1] and Gap[2] are facing accusations of violating the Arizona Act by embedding analytics technologies, referred to as "spy pixels" in the complaints, in emails without obtaining consumers' consent. Plaintiffs assert that the data collected, including information on email opening times and locations, frequency of interactions, forwarding, printing and recipient email server types, constitutes "communication service records" under Arizona Act. These data points are very widely used in digital marketing. While many of these cases are currently in the motion-to-dismiss stage, companies using tracking technologies in their email marketing campaigns should be wary of potential lawsuits from Arizona consumers.

Additionally, there has been an uptick in website privacy cases under the Song-Beverly Credit Card Act, a California law established in 1971. These lawsuits allege that gathering personal information, including IP addresses, during online credit card transactions violates the Act's prohibition on requiring the provision of personal information in exchange for completing a credit card transaction. This raises questions about the definition of "necessary data" permissible under the statute and whether IP addresses constitute personally identifiable information (PII) under California law. This intersection of Song-Beverly and Pixel cases is a prime example of how the plaintiff bar is adapting old laws to regulate new technologies.

The outcomes of these lawsuits will shape future litigation strategies and provide valuable guidance for companies looking to refine their data collection practices to mitigate legal risks. As we approach 2025, it is crucial for businesses to proactively assess and adapt their data privacy policies and compliance these evolving legal precedents. By staying informed about the implications of recent rulings, companies can better anticipate potential challenges and adapt their strategies accordingly.

10. **Avoid Becoming a "Web Wiretapping" Target**

Many website owners mistakenly believe that if they have a California Consumer Privacy Act (CCPA)-compliant website and privacy policy, they are immune to these claims. To be CCPA-compliant means, among other things, that the website protects the data privacy rights of California residents as outlined under CCPA. However, most website invasion of privacy cases do not bring claims under the CCPA, and the CCPA does not require the types of consents and mechanisms that will enable website owners to thwart these claims.

Even if all the tracking technologies deployed on a website are clearly disclosed in a posted privacy policy and a cookie banner allows users to select cookie preferences, it becomes a challenge to argue that prior consent exists if those tracking technologies are firing *before* the website users have given their prior informed consent.

What about implied consent? While consent can be either express or implied,[4] implied consent is often difficult to argue in the case of a typical consumer. Many plaintiffs' firms employ "tester plaintiffs" to bring these claims, similar to the wave of tester plaintiffs in the heyday of Americans with Disabilities Act (ADA) website lawsuits. These plaintiffs appear to visit websites specifically to identify those that may be vulnerable to privacy violation claims. It can be argued that a privacy tester plaintiff, who intentionally enters data with the expectation that it may be "stolen" or subject to eavesdropping under the CIPA statute, has impliedly consented to such conduct. If you find yourself facing these challenges, consider consulting experienced web wiretapping counsel who can help develop this argument.

At least one court has expressed disapproval of the use of "testers" to bring these claims in mass: "When the goal is to file as many lawsuits as possible in the least amount of time, it is far easier and cheaper to copy and paste a complaint over and over again, and to write the original template in such a way that hardly anything needs to be swapped out. … And surely, whatever one's views on the propriety of copying and pasting from boilerplate pleadings, there is a point at which all reasonable people should agree the practice has gone too far."[5] Despite this, cases involving "tester" plaintiffs continue to be filed and accepted by the courts, at least for now.

To proactively avoid these claims, we recommend the following strategies:

- Hold regular meetings between marketing and legal teams to ensure a full understanding of the technology being used and how to mitigate associated liabilities.
- Obtain additional technical advice if the marketing team does not fully understand how the tracking technologies operate.
- Review all website technology use to ensure third-party vendors cannot use consumer data for their own purposes without consent.
- Review and revise privacy policies regularly to ensure that they are comprehensive and accurate.
- Regularly review the tracking technologies active on your website to ensure that each one serves a current important purpose and is described in the privacy policy.
- Assess website chat features to ensure that the website owner is gathering explicit consent to the chat to be recorded and/or shared.
- Obtain affirmative, express consent from users for the specific types and purposes of data collection, such as using a banner that requires explicit, trackable consent to the terms and policies disclosing the software on the site before it is deployed.

11. The Need for Experienced Counsel in Privacy Law and Litigation

The Cybersecurity and Data Privacy team at Buchanan delivers comprehensive strategies for managing data privacy and cybersecurity challenges. We specialize in both compliance and litigation, with extensive experience in handling website wiretapping issues, including tracking and tracing. Our team has defended clients in a variety of contexts, from mass arbitrations to

class actions, in courts nationwide. Our approach focuses on understanding our clients' business and marketing objectives, working collaboratively to achieve those goals while mitigating data privacy risks. Additionally, we offer a flat fee website auditing service designed to identify potential areas of risk and exposure. For more information about our flat-fee auditing service, click here to view our brochure, and reach us at cyber@bipc.com.

1. *Smith v. Target Corporation*
2. *Carbajal v. Gap Incorporated et al.*
3. *Schneckloth v. Bustamonte*, 412 U.S. 218, 227 (1973)
4. *Byars v. Hot Topic, Inc.,* 656 F. Supp. 3d 1051, 1060 (C.D. Cal. 2023)

Article Title: New NYSE and Nasdaq Listing Requirements

Category: Corporate

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Link: https://www.bipc.com/new-nyse-and-nasdaq-listing-requirements?utm_source=advisory&utm_medium=email&utm_campaign=2025-02-03_Corporate

Summary: Recently, the SEC approved rules proposed by the Nasdaq Stock Market and the New York Stock Exchange that permit the exchanges to accelerate the delisting process for companies that fail to maintain a $1 minimum share price.

Each exchange adopted new rules affecting companies that utilize reverse stock splits to maintain their minimum price requirements.

Learn more about the new rule modifications, including key takeaways and implications for companies listed on these exchanges.

Article:

Introduction

Recently, the SEC approved rules proposed by the Nasdaq Stock Market (Nasdaq) and the New York Stock Exchange (NYSE) that permit the exchanges to accelerate the delisting process for companies that fail to maintain a $1 minimum share price. Each exchange adopted new rules affecting companies that utilize reverse stock splits to maintain their minimum price requirements. Nasdaq also accelerated the delisting process for companies that fail to remedy a minimum bid price compliance issue within 360 days of notice of the deficiency. The new rule modifications thus aim to enhance investor protection while ensuring that companies listed on these exchanges can demonstrate actual financial stability without using reverse stock splits as a means to evade regulatory intervention.

Nasdaq Rule Changes

Under previous Nasdaq listing standards, companies were required to maintain a minimum bid price of $1.00 per share. If a company's share price fell below this threshold for 30 consecutive business days, Nasdaq would notify the company, granting it a compliance period of 180 calendar days to rectify the deficiency. If the company failed to comply within this timeframe, it could potentially be eligible for a second 180-day compliance period, particularly if it notified Nasdaq of its intent to cure the deficiency through means such as a reverse stock split. Following the second 180-day compliance period, mechanisms existed for a company to request a further stay of the delisting, such as through a request for a hearing.

On January 17, 2025, the SEC issued a Notice approving Nasdaq's proposal to modify Listing Rule 5810(c)(3)(A), which governs minimum bid price compliance periods and delisting processes. Under the new rules, if a company fails to regain compliance with the minimum bid price requirements during the aggregate 360-day compliance period, it will face immediate suspension and delisting from Nasdaq, with no additional grace period provided. Additionally, if a company falls below the minimum bid price requirement for continued listing and has executed a reverse stock split within the prior year, it will not be eligible for any compliance periods and will receive an immediate delisting determination.

The rule will force companies to be more strategic in their approaches to compliance, ensuring that any actions taken to meet the bid price requirement do not inadvertently violate other listing standards. As per Nasdaq’s findings cited in the Notice, patterns of haphazard reverse stock splits often indicate deeper operational issues, which are likelier to render a company unsuitable for listing. By strengthening restrictions on stock value thresholds, Nasdaq aims to prevent companies, particularly those in financial distress, from repeatedly using reverse stock splits as a means to avoid delisting.

NYSE Rule Changes

The NYSE has also instituted similar changes to its compliance rules, which were approved by the SEC on January 15, 2025. Previously, if a company's shares fell below an average closing price of $1.00 over 30 trading days, the company had six months to cure the defect. Under the revised Section 802.01C of the NYSE Listed Company Manual (the Manual), a company that fails to meet this minimum Price Criteria now will not be eligible for a compliance period if it has executed a reverse stock split within the past year or if it has conducted multiple reverse splits with a cumulative ratio of 200 shares or more to one within the past two years. In such cases, the NYSE will begin immediate suspension and delisting procedures.

Additionally, the NYSE modified its rules to initiate immediate suspension and delisting procedures if a company regains Price Criteria compliance only through a reverse stock split, which then causes a violation of another of the Manual's Section 802.01A listing requirements. This regulatory approach mirrors Nasdaq's objective of preventing companies from using reverse stock splits as a temporary fix for underlying financial issues.

Both exchanges justify these changes as necessary measures to enhance listing standards and protect investors from companies that may be engaging in manipulative practices to maintain their listings.

Conclusion

The recent approval by the SEC of the regulatory changes to Nasdaq and NYSE's minimum price compliance rules signify a more stringent approach to investor protection. Companies listed on these exchanges must now navigate stricter oversight when considering reverse stock splits as a compliance strategy. Issuers facing low share prices must be attentive to these new rules, as non-compliance could lead to swift delisting actions. As these regulations take effect, companies are encouraged to develop proactive strategies to ensure compliance and safeguard their listings.

Article Title: National Security Tariffs on Steel and Aluminum Imports

Category: International Trade & National Security

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Link: https://www.bipc.com/national-security-tariffs-on-steel-and-aluminum-imports?utm_source=advisory&utm_medium=email&utm_campaign=2025-02-13_International_Trade

Summary: On February 10 and 11, 2025, President Trump issued two Presidential Proclamations that impose 25% national security tariffs on imported articles of steel, derivative steel articles, aluminum articles, and derivative aluminum articles (collectively, "232 Tariffs").

Applicable beginning on March 12, 2025, the Proclamations impose the tariffs by nullifying exemptions to various countries, reinstating and expanding steel and aluminum tariffs, and raising aluminum tariffs.

Learn more about the 232 Tariffs, including takeaways for the steel and aluminum industry.

Article:
On February 10 and 11, 2025, President Trump issued two Presidential Proclamations that impose 25% national security tariffs on imported articles of steel, derivative steel articles, aluminum articles, and derivative aluminum articles (collectively, "232 Tariffs").[1] These actions aim "to protect America's steel and aluminum industries, which have been harmed by unfair trade practices and global excess capacity."[2] Applicable beginning on March 12, 2025, the Proclamations impose the tariffs by nullifying exemptions to various countries, reinstating and expanding steel and aluminum tariffs, and raising aluminum tariffs.

Under the Steel Proclamation, the 232 Tariffs will cover steel articles imports under Harmonized Tariff Schedule US (HTSUS) subheading 9903.80.01.[3] In addition, the Proclamation rescinds certain exemptions from 232 Tariffs on steel articles and derivative steel articles by Argentina, Australia, Brazil, Canada, the European Union member countries, Japan, Mexico, South Korea, and Ukraine. Of particular importance, the additional derivative steel articles covered by the Steel Proclamation shall be subject to the *ad valorem* duties proclaimed in Proclamation 9705 and Proclamation 9980, except for derivative steel articles processed in another country that are made from steel articles that were melted and poured in the United States.[4]

The Aluminum Proclamation modifies Proclamation 9704 by increasing the *ad valorem* duty rate on covered imports of derivative aluminum articles from 10% to 25%. The tariff rate on imports of aluminum from Russia will be 200%. These rates of duty, which are in addition to any other duties, fees, exactions, and charges applicable to such imported derivative aluminum articles,

shall apply to imports of derivative aluminum articles described in Annex I to the Aluminum Proclamation from all countries, except for derivative aluminum articles processed in another country from aluminum articles that were smelted and cast in the United States.[5]

Further, in an effort to bolster the effectiveness of the 232 Tariffs, the Steel Proclamation and Aluminum Proclamation eliminate the product exclusion processes that had previously been authorized under Proclamations 9704, 9705, and 9980. As a result, it appears that importers will find it more difficult to bypass the 232 Tariffs.

While these 232 Tariffs are set to establish an important national security protection for U.S. steel and aluminum producers, it is important to note that this initial trade action also provides opportunity for producers to seek inclusion of additional derivative steel and derivative aluminum articles. Within 90 days from the date of the proclamations, the U.S. Department of Commerce (Commerce) is required to establish a process for certain parties to request including additional articles within the scope of 25% duties proclaimed in Proclamations 9704, 9705, and 9980. Within 60 days of receiving any such request, Commerce will be required to issue a determination on whether or not to include the article. This is a critical opportunity for domestic producers of steel articles, derivative steel articles, aluminum articles, derivative aluminum articles, or industry associations representing such producers to assess whether products would benefit from the imposition of 232 Tariffs.

Buchanan has a team of international trade and national security attorneys, and government relations professionals ready to help U.S. manufacturers with U.S. trade remedy laws and trade policy. U.S. AD/CVD tariff laws are one of the only available tools to reestablish an even playing field for American companies and avoid lost sales and profits. Our eBook, Protecting Domestic Producers: A Guide to Antidumping and Countervailing Investigations, shares details on how diverse domestic industries can take advantage of these laws – antidumping and countervailing duty investigations – to combat unfair foreign competition and receive adequate remedies and protections. Our dedicated team has decades of experience supporting clients across a range of industries – ranging from steel, chemical, rubber, mining, and agricultural products – to ensure that the U.S. market is operating under fair and equal conditions.

1. *See Adjusting Imports of Steel Into the United States*, The White House (February 10, 2025) (the "Steel Proclamation"); *see also Adjusting Imports of Aluminum Into the United States*, The White House (February 11, 2025) (the "Aluminum Proclamation").

2. *Fact Sheet: President Donald J. Trump Restores Section 232 Tariffs*, The White House (February 11, 2025).

3. *See* Steel Proclamation; *see also* Aluminum Proclamation.

4. Steel Proclamation at Annex I.

5. Aluminum Proclamation at Clause 5 and Annex I.

Article Title: President Trump and Reciprocal Trade and Tariffs

Category: International Trade & National Security

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Date: 2/17/25

Link: https://www.bipc.com/president-trump-and-reciprocal-trade-and-tariffs?utm_source=advisory&utm_medium=email&utm_campaign=2025-02-17_International_Trade

Summary: On February 13, 2025, the Trump administration announced it will begin a comprehensive review of duties imposed on U.S. exports to pursue a policy of reciprocal trade.

The Reciprocal Trade and Tariffs Memorandum provides a framework to potentially initiate a global trade reconfiguration.

Learn more about this Memorandum, including takeaways on the plan to establish reciprocal trade and next steps.

(a) Article:

Background

On February 13, 2025, the Trump Administration announced it will begin a comprehensive review of duties imposed on U.S. exports to pursue a policy of reciprocal trade.[1] In a corresponding memorandum on Reciprocal Trade and Tariffs, President Trump directed several federal agencies to commence a broad review of tariffs and non-tariff barriers that U.S. trading partners impose on U.S. exports and to recommend reciprocal duties.[2] The comprehensive review and corresponding recommendations may reflect the administration's aim to methodically develop an enduring reconfiguration of global trade based on reciprocity that is consistent with its America First Trade Policy.[3]

12. **A Plan to Establish Reciprocal Trade**

The Reciprocal Trade and Tariffs Memorandum provides a framework to potentially initiate a global trade reconfiguration. First, it clarifies that U.S. trade policy will be to reduce its "large and persistent annual trade deficit in goods and to address other unfair or unbalanced aspects of our trade with foreign trading partners."[4] To accomplish this policy, the Memorandum introduces the "Fair and Reciprocal Plan."[5] The Plan directs certain federal agencies to examine non-reciprocal trade relationships with all U.S. trading partners, including review of:

- Tariffs and non-tariff barriers such as subsidies or technical barriers to trade,
- Value-added tax and other taxes,
- Mercantilist policies that impede American competitiveness in foreign markets, such as distortive foreign exchange rates and wage suppression, and
- Any other practice or structural impediment that the United States Trade Representative (USTR) judges imposes unfair limitations on foreign market access or impedes fair competition.

After the Federal agencies have submitted their America First Trade Policy reports, which are due on April 1, the U.S. Secretary of Commerce and the USTR shall initiate all necessary actions to investigate harm to the United States from non-reciprocal trade. After completing these actions, Commerce and USTR are then required to submit a report proposing remedies to the President. Notably, the Reciprocal Trade and Tariffs Memorandum does not identify a date when Commerce and USTR will submit this report to the President. Further, the Memorandum does not clarify whether or what action will be taken following receipt of the report.

13. **Next Steps**

While the Memorandum provides a framework for identifying trade imbalances and remedial actions that the U.S. government could take, it does not provide a timeframe for such action. Accordingly, unlike the 25% national security tariffs on articles of steel and aluminum and their derivatives that are effective beginning March 12, 2025, there remain open questions as to the timing of next steps and what type of trade relief can be expected. Despite these issues, it is clear that fair trade remains an important priority for this Administration. As such, this could be an important time to consider what options for trade relief are available.

Buchanan has a team of international trade and national security attorneys, and government relations professionals ready to help U.S. manufacturers with U.S. trade remedy laws and trade policy. U.S. Antidumping and Countervailing tariff laws are one of the only available tools to reestablish an even playing field for American companies and avoid lost sales and profits. Buchanan's eBook, Protecting Domestic Producers: A Guide to Antidumping and Countervailing Investigations, shares details on how diverse domestic industries can take advantage of these laws – antidumping and countervailing duty investigations – to combat unfair foreign competition and receive adequate remedies and protections. Our dedicated team has decades of experience supporting clients across a range of industries – ranging from steel, chemical, rubber, mining, and agricultural products – to ensure that the U.S. market is operating under fair and equal conditions.

1. *Fact Sheet: President Donald J. Trump Announces "Fair and Reciprocal Plan" on Trade*, The White House (February 13, 2025).
2. *See* Memorandum for Certain Executive Agencies, *Reciprocal Trade and Tariffs*, The White House (February 13, 2025) ("Reciprocal Trade and Tariffs Memorandum").

3. *See* Memorandum for Certain Executive Agencies and Executive Advisors, *America First Trade Policy*, The White House (January 20, 2025).

4. Reciprocal Trade and Tariffs Memorandum at Section 2.

5. *Id.*

Article Title: Recent Developments in New Jersey and New York Are Likely to Increase AI Driven Employment-Discrimination Litigation

Category: Labor & Employment

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Date: 2/18/25

Link: https://www.bipc.com/recent-developments-in-new-jersey-and-new-york-are-likely-to-increase-ai-driven-employment-discrimination-litigation?utm_source=advisory&utm_medium=email&utm_campaign=2025-2-13_Labor_Employment?utm_source=advisory&utm_medium=email&utm_campaign=2025-02-18_Labor_Employment

Summary: New agency guidance and pending legislation in New Jersey and New York may heighten the legal risks for employers using AI in hiring practices, with strict liability for discriminatory outcomes and potential mandatory disclosures to applicants.

To understand how these changes could impact recruitment strategies, read more about the implications of the recent NJLAD Guidance and the New York AI Act.

Article:
As the comprehensive federal Algorithmic Accountability Act—first introduced in 2019—slowly progresses (or not) through Congress, individual states are actively responding to reports of algorithmic bias in employment decisions, swiftly enacting their own laws and guidance to combat AI-enabled bias in recruiting, screening, and hiring employment applicants. Most recently, in January 2025, the New Jersey Division on Civil Rights published a Guidance on Algorithmic Discrimination and the New Jersey Law Against Discrimination (the "NJLAD Guidance" or the "Guidance"). At the same time, the State of New York introduced legislation (S.B. 1169) (the "New York AI Act" or the "Act"), which would require companies using AI in

recruiting and hiring processes to independently audit and evaluate their systems for algorithmic bias in employment practices. These state-level developments may create increased risks to employers using AI tools in recruiting, screening, and hiring applicants.

14. The NJLAD Guidance Puts Employers on Explicit Notice That They Are Liable for AI-Driven Employment Discrimination

The Guidance mirrors the NJLAD's prohibition of discrimination in employment decisions based race, religion, color, national origin, sexual orientation, pregnancy, breastfeeding, sex, gender identity, gender expression, disability, and other protected characteristics. Consequently, covered Employers may be held liable for discriminatory employment decisions arising from the use of AI tools, *even if* they did not develop the tool or are unaware of its discriminatory mechanisms.

This is likely to affect more than half of New Jersey Employers; a recent Rutgers University survey cited in the Guidance found that 63% of the 233 Employers surveyed—averaging 400 employees and representing various sectors such as manufacturing, wholesale and retail trade, finance, healthcare, education, and government—use one or more AI tools in recruiting and selecting employees. The most commonly used AI tools include applicant-tracking software from LinkedIn, Workday, ADP, ZipRecruiter, iCIMS, and Greenhouse for drafting job postings, organizing resumes, and tracking candidates through the hiring process. Additionally, Employers frequently use AI tools to make decisions about promotions, demotions, or terminations.

The NJLAD Guidance aligns with, but is more expansive than, the federal EEOC Guidance issued in May 2023, which cautioned that Employers may be liable for discriminatory practices in recruitment, monitoring, transferring, and evaluation resulting from AI tools. However, unlike the NJLAD Guidance, the EEOC Guidance is limited to disparate-impact claims and does not encompass disparate treatment claims. And the long-term viability of the EEOC Guidance is uncertain under the new Administration.

Covered AI and Algorithmic Discrimination Under the NJLAD Guidance

While AI and AI tools are enormously broad terms, the NJLAD Guidance specifically covers "any technological tool, including but not limited to, a software tool, system, or process that is used to automate all or part of the human decision-making process." Further, the Guidance emphasizes that Employers may not shirk liability by blaming an AI tool vendor for a discriminatory outcome that forms the basis of a lawsuit.

Disparate Treatment, Disparate Impact, and Reasonable Accommodations Under the NJLAD Guidance

Additionally, the Guidance explains that Employers may be liable under either a theory of disparate-treatment discrimination or disparate-impact discrimination. An Employer may be liable for disparate-treatment discrimination where the Employer uses AI tools to treat members of a protected class differently based directly on a protected characteristic, or indirectly based on a close proxy for a protected characteristic. An example of disparate-treatment discrimination would be an applicant-screening tool designed to prefer applicants who provide individual taxpayer identification numbers instead of Social Security numbers because the Employer wants to hire immigrants based on its belief that immigrants will be less likely to challenge unlawful

working conditions. On the other hand, an Employer may be liable for disparate-impact discrimination where it relies on the recommendations of an AI tool that are facially neutral and not motivated by discriminatory intent but result in employment decisions that disproportionately harm members of a protected class, unless the AI tool serves a substantial, legitimate, nondiscriminatory interest. By way of example, an applicant-screening tool for a delivery service that disproportionately screens out applications from women based on a belief that men are stronger and thus more suitable for the delivery job could run afoul of disparate-impact prohibitions. However, even where the AI tool serves a substantial, legitimate, nondiscriminatory interest, an Employer may still be liable if there is a less discriminatory alternative.

Finally, the Guidance covers AI-driven discrimination for failure to provide a reasonable accommodation for an applicant's or employee's known or reasonably apparent disability, religion, pregnancy, or breastfeeding. This may happen where an AI tool is inaccessible to individuals with a protected characteristic (*e.g.*, an Employer uses an AI tool to measure applicants' typing speed, which cannot measure the typing speed of an applicant with a disability who must use a non-traditional keyboard) or where an AI tool makes recommendations without factoring in a reasonable accommodation (*e.g.*, an Employer uses an AI tool to measure employees' productivity based on break times and adopts recommendations for discipline or promotion based without considering reasonable accommodations for protected employees to allow for additional break time).

15. **The New York AI Act Creates Novel Employer Obligations and Private Rights to Sue**

Unlike the NJLAD Guidance, which extends existing anti-discrimination protections to Employers' use of AI tools, the New York AI Act would establish new obligations for Employers to actively prevent AI-driven employment discrimination. It also broadens the definition of protected characteristics under State law for the purposes of the Act to include height and weight.

Employers Would Need to Provide Notice and Opt-Out Options Before Utilizing AI Tools

Most notably, the Act would require Employers to provide employees and applicants with at least five (5) business days' notice in clear, consumer-friendly terms before using AI tools to make employment decisions. Additionally, applicants and employees must have the ability to opt out of the AI process and request that a human representative make the decision instead. If an employee or applicant waives the five-day notice, Employers would still need to provide one (1) business day of notice before using an AI tool, along with the opportunity to opt out. Employers would also be required to allow appeals for any decisions made entirely by or with the assistance of an AI tool. The Act specifies that employers are liable for any bias resulting from the use of AI tools.

Employers Would be Required to Commission AI-Discrimination Auditors and File Reports With the Attorney General

The Act would also impose significant third-party audit and reporting obligations before Employers can use AI tools to make employment decisions. Employers would have to conduct audits six (6) months after deployment and every eighteen (18) months thereafter. These audits

must analyze discriminatory disparate impacts, and Employers are prohibited from hiring any third-party auditors who have provided services to them in the past twelve (12) months. Additionally, Employers would be required to file reports with the Attorney General and establish comprehensive risk-management policies to prevent AI-driven employment discrimination.

Employers Could Be Liable Absent Actual Injury

The Act would empower the Attorney General to seek injunctions in New York State Supreme Court to enforce its provisions, imposing civil penalties of up to $20,000 for each violation without requiring proof of injury. New York residents could also bring private actions for harm caused by violations of the Act, entitling them to compensatory damages and legal fees if they prevail. Moreover, the Act includes whistleblower protections, granting employees and applicants rights to injunctive relief, reinstatement, compensatory damages, and punitive damages.

16. **Potential Consequences: Increased Litigation Against NJ and NY Employers for AI-Driven Employment Discrimination**

The NJLAD Guidance and New York AI Act, if passed, *may* result in an increase of AI-based employment-discrimination lawsuits, particularly in New York. To date, there have been few precedential cases on AI-driven employment-discrimination claims. However, two recent cases provide some insight into how courts may treat such actions.

In August 2023, the EEOC secured its first AI-bias settlement in New York after charging iTutorGroup, a tutoring services company, with age discrimination. The agency alleged that the company programmed its application review software to automatically reject female applicants aged 55 or older and male applicants aged 60 or older.

Then, on July 12, 2024, a California federal judge declined to dismiss a putative class action brought against Workday, a major human capital management platform, claiming it is directly liable under Title VII for discrimination caused by its applicant-screening AI tools. The lawsuit alleges that Workday's screening tools discriminated based on race, age, and disability. The EEOC filed a friend-of-the-court brief urging the federal court not to dismiss the action while Workday's motion to dismiss was pending. The case has since moved to discovery and remains under litigation.

In the last year, class actions related to algorithmic discrimination beyond employment decisions have also emerged. In December 2023, the Federal Trade Commission (FTC) announced a settlement with Rite Aid in a lawsuit arising from the company's use of AI-based facial recognition technology. Additionally, in April 2024, tenant-screening service SafeRent Solutions entered a $2.28 million settlement agreement in a class action after Massachusetts rental applicants alleged that the company's AI-based screening tool discriminated on the basis of race.

17. **Takeaways**

The onerous requirements and significant litigation risks caused by the Act will force New York Employers—including those that employ remote workers residing in New York—to reconsider

whether the benefits of AI tools in recruiting, hiring, or other employment practices justify the costs and risks under the Act. Additionally, New Jersey Employers should immediately revisit their use of and policies on AI tools in employment processes and decisions to protect themselves from liability.

Buchanan's Labor and Employment, Class Actions, Advanced Technology, Cybersecurity & Data Privacy, and Government Relations teams continue to monitor the latest developments and stand ready to assist Employers with ensuring that their policies and practices address federal and State governments' evolving position on prohibited AI-driven employment discrimination.

Article Title: Department of Commerce Pauses Processing of All New Export License Applications

Category: International Trade & National Security

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Link: https://www.bipc.com/department-of-commerce-pauses-processing-of-all-new-export-license-applications

Summary: The Bureau of Industry and Security (BIS), the export licensing arm of the Department of Commerce, has reportedly paused processing of all new export license applications without explanation, according to multiple sources within the industry and further confirmed by Buchanan's team of export compliance attorneys.

License applications filed with BIS from the beginning of February onward will be paused for processing and review.

Learn more about this pause, including takeaways for companies involved in international commerce.

Article: The Bureau of Industry and Security (BIS), the export licensing arm of the Department of Commerce, has reportedly paused processing of all new export license applications without explanation, according to multiple sources within the industry and further confirmed by Buchanan's team of export compliance attorneys.

License applications filed with BIS from the beginning of February onward will be paused for processing and review. BIS licensing officers have confirmed that the agency was told to "hold without action" all new export license applications filed after February 5, 2025. The agency has not issued a formal statement or any other form of guidance for what industry can expect for recently filed applications or applications that will be submitted in the coming weeks and months.

The pause comes as a result of an apparent review of policy that has immediate implications for the industry. With no guidance or statement issued by BIS, industry has no clear standard with which to operate, and this pause will undoubtedly extend already lengthy license application review timelines. This pause is not expected to implicate license applications filed with the Directorate of Defense Trade Control (DDTC).

Buchanan reached out to officials at BIS and confirmed that the pause is currently in effect and at this time does not have an expected end date. The official noted that certain urgent license applications may be able to push through the pause and proceed to adjudication.

Buchanan's team of National Security attorneys possesses extensive experience in advising on export control policies and is well-prepared to assist clients in navigating the implications of this licensing pause.

Article Title: Corporate Transparency Act Reporting Back On

(For Now)

Category: Corporate

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Date: 2/20/25

Link: https://www.bipc.com/corporate-transparency-act-reporting-back-on-(for-now)?utm_source=advisory&utm_medium=email&utm_campaign=2025-02-20_Corporate

Summary: As a result of a February 17, 2025 decision by the U.S. District Court for the Eastern District of Texas in Smith, et al. v. U.S. Department of the Treasury, et al., the beneficial ownership information (BOI) reporting requirements under the Corporate Transparency Act (CTA) are once again back in effect.

The Financial Enforcement Crimes Network (FinCEN) has extended the deadline for filing initial, corrected, and updated reports under the CTA to March 21, 2025.

Learn more about key takeaways and implications for reporting companies.

Article:A*Smith, et al. v. U.S. Department of the Treasury, et al.*, the beneficial ownership information (BOI) reporting requirements under the Corporate Transparency Act (CTA) are once again back in effect.

The Financial Enforcement Crimes Network (FinCEN) has extended the deadline for filing initial, corrected, and updated reports under the CTA to March 21, 2025. If a reporting company currently has a filing deadline after March 21, 2025, because of, among other things, FinCEN's earlier hurricane disaster reporting relief, that later deadline will continue to apply.

However, this is certainly not the end of the story. In providing this extension, FinCEN stated that during this 30-day extension, it will assess its options to further modify deadlines while prioritizing reporting for those entities that pose the most significant national security risks.

FinCEN also stated that it intends to initiate a process this year to revise the CTA reporting requirements to reduce the burden for lower-risk entities, including many U.S. small businesses.

In a legislative development, the United States House of Representatives passed H.R. 736, the Protecting Small Businesses from Excessive Paperwork Act of 2025, that would extend the reporting deadline to January 1, 2026, for reporting companies formed before January 1, 2024. Companion legislation, S. 505, has been introduced by the Senate Banking Committee Chairman, Senator Tim Scott (R-SC). Senate consideration of the S. 505 has yet to be scheduled.

As a result, there currently remains the possibility that the filing deadlines will be further extended and that certain types of reporting companies will be relieved from the BOI reporting obligations entirely.

We recommend that companies that are not currently exempt from the CTA reporting requirements complete their BOI reports now and be prepared to submit them to FinCEN as the March 21 deadline approaches.