

Drinker Biddle

One Year In, Elections Have Consequences

Regulatory Affairs Webinar 2018

Introduction

Mary Devlin Capizzi

Overview of the webinar's objectives:

- Examine the first year of the Trump administration
- Evaluate predictions for federal agencies and policy in 2018
- Discuss policy implications for health care, customs and trade, environment and energy, education, intellectual property, data privacy and telecommunications

CLE Code: Regulatory Affairs Elections Webinar 2018

Policy Updates: General Overview & Health Care

Jodie Curtis and Jeremy Scott, District Policy Group

2017 was slow on nominations and there was whiplash and surprise on many policies. There was high turnover in the White House and federal agencies. A fractured Congress made many legislative efforts difficult but the ACA repeal was able to pass. Towards the end of the year, tax reform and investigations in the government took to the forefront.

In overall policy for 2018, President Trump is likely to stick to big issues -- smaller issues and initiatives will bubble up from Congress and agencies. Since it's an election year, Congress is likely to be done by June or July. Expect more turnover, more nominations and more deregulation. We do not expect that there will be major action on the ACA or entitlements. Other issues include immigration, the debt ceiling, infrastructure, foreign affairs, the Farm Bill and further investigations.

In health care policy for 2018, there will be a focus on funding the government, the opioid crisis, questions on drug supply chain, 340B drug pricing, efforts from HHS Secretary Azar, the appointment of a new CDC Director, Alexander-Murray, HHS regulations, FDA guidance and Right to Try.

The First Year of the Trump Administration's National Security & Trade Policy

Nate Bolin and Nick Guzman

The New Administration's National Security Policy

- The Trump Administration is in the midst of a wholesale realignment of U.S. trade policy regarding China.

- 2017 saw increasing efforts to counter Chinese efforts to acquire sensitive technology and manufacturing know how, and these efforts will continue in 2018 through mechanisms like national security reviews of foreign investment conducted by the Committee on Foreign Investment in the United States (CFIUS)
- A record number of deals have been put on hold or blocked by CFIUS and the CFIUS mechanism may see an expanded role as a trade policy enforcement mechanism.
- New CFIUS Legislation known as the Foreign Investment Risk Review Modernization Act (FIRRMA) has strong bipartisan support and may be passed in 2018. It will make many more transactions subject to CFIUS reviews, including transactions taking place outside the United States that involve U.S. intellectual property and the personal data of U.S. citizens.

Changes to U.S. Export Controls and Sanctions

- Congress has taken an unusually active role in expanding and demanding enforcement of U.S. sanctions on Russia, North Korea, and Iran, passing the Countering America's Adversaries Through Sanctions Act (CAATSA) in August 2017. CAATSA codified the Obama Administration's sanctions on Russia and imposed additional sanctions and reporting requirements.
- U.S. Customs has expanded responsibilities under CAATSA to enforce U.S. secondary sanctions on North Korea.-- Many companies will be impacted by the requirement that importers certify that their products are not made with North Korean forced labor or North Korean inputs.
- Export Control Reform is largely complete, but some changes to key definitions and requirements are likely to be implemented in 2018. There may also be significant revisions of the U.S. International Traffic in Arms Regulations as a result of an on-going regulatory review.

Trade Policy Under Trump

- China – The trade deficit with China and Chinese trade policies have been the central theme of the Trump administration's efforts to reshape and redirect U.S. trade policy
- Sections 201, 232 & 301. The Trump Administration has been employing these historically rarely-used statutes to address what it sees as trade that is harming U.S. national security or otherwise impinging on the viability of certain industries. Additional duties and import restrictions on solar panels and washing machines were recently imposed under the Section 201 statute, a review of China's compliance with its obligations to protect U.S. intellectual property is on-going under Section 301, and three cases have been initiated under Section 232, alleging that imports of steel,

aluminum, and uranium are harming U.S. national security.

- Antidumping and Countervailing Duties (AD/CVD) – 2017 was a record year for AD/CVD investigations and increased enforcement of AD/CVD orders by U.S. Customs. This pace looks set to continue for 2018.
- No More Multilateral FTAs – The United States has withdrawn from the Trans-Pacific Partnership (TPP) and has not been proceeding with negotiations with the EU under the proposed Transatlantic Trade and Investment Partnership (TTIP) framework, but the Trump Administration may reconsider the decision to pull out of the TPP entirely.
- Bilateral FTAs – The Trump Administration is seeking to move away from multilateral trade agreements to a series of bilateral agreements with Japan, the U.K. and possibly countries in Africa. The Trump Administration is likely to request the extension of existing “Trade Promotion Authority” when it expires in June 2018 to enable these and other FTA negotiations to continue.
- NAFTA Negotiations have been ongoing but progress has been slow. The possibility continues that the Trump Administration may withdraw the United States from NAFTA.
- The Trump Administration has repeatedly criticized the dispute settlement mechanism at the WTO and the overall failure of the WTO to address what it sees as state-directed mercantilism on the part of China and Russia. In recent reports on these country’s compliance with their WTO obligations, the U.S. Trade Representative stated that the United States “erred” by allowing China and Russia to join the WTO. Expect more stalemate and little progress in resolving the on-going trade disputes at the WTO.

Our Customs and International Trade team regularly distributes client alerts regarding export controls, CFIUS, national security, economic sanctions AD/CVD investigations and orders and other important developments in U.S. customs and trade law. To sign up for the list, please contact a member of the Customs and International Trade team.

U.S. EPA Update

Bonnie Barnett

Four key areas: enforcement, superfund work, water regulations and downsizing of the U.S. EPA.

President Trump has slowed down actions against pollution and placed limits on enforcement officers. Under Secretary Pruitt, there have been 1900 civil cases, 1/3 fewer than President Obama and 1/4 fewer than President Bush. Civil penalties have come in at \$50 million, 40% less than President Obama and 70% less than President Bush.

There has been a decrease in superfund work with fewer sites being listed. President Trump plans to push work down to the states. This administration is largely development-driven and has shown to be surprising.

For water regulations enforcement, the U.S. EPA has not added a chemical to drinking water standards in 10 years. There are emerging concerns with contaminants and wetlands issues.

There have been 700 departures from the U.S. EPA since President Trump took office. Some regions have faced a hiring freeze for the last 4 years. Replacement policies are yet to be seen and 15 lawyers have departed Region 3 under Trump. The lack of personnel adversely impacts the ability to further the EPA’s agenda.

Education: Federal Regulation and Policy Activity

Jonathan Tarnow

Despite significant delays in filling senior leadership positions, the U.S. Department of Education has undertaken several significant policy initiatives in the first year of the new administration. Title IX is a notable example, where in February 2017 the Departments of Justice and Education withdrew guidance from May 2016 regarding transgender student rights, and in September 2017 the Department of Education withdrew 2011 and 2014 sub-regulatory guidance regarding campus sexual harassment and assault matters. In lieu of continued letter guidance, the Department intends to promulgate formal regulations on these matters.

The current administration has initiated negotiated rulemaking proceedings to revise two significant higher education regulations from the Obama administration: “gainful employment” and “borrower defense to repayment.” The outcome of these rulemakings is expected sometime during the spring or summer of 2018, with new regulations to be finalized by the fall and take effect in July 2019.

Legislatively, there is a focus on reauthorizing the Higher Education Act, the primary federal law governing postsecondary education in the United States. Both the House and Senate education committee chairs seek to streamline and simplify federal student financial aid programs, while also to incentivize colleges and universities to do more to ensure student success. The House has passed a bill out of committee that is pending floor consideration, and a Senate bill is expected to be introduced in the coming weeks.

The recent “Tax Cuts and Jobs Act” included a 1.4% excise tax on investment income at private colleges with an enrollment of at least 500 students and with assets valued at \$500,000 per full-time student.

The Education team regularly distributes client alerts on a variety of developments and policy updates. To join the mailing list, please contact a member of the Education team.

Two of our most recent alerts include, [“U.S. Department of Education Withdraws Select Obama-era Title IX Policy and Guidance Statements,”](#) and, [“Higher Education Act Reauthorization Moves Forward Into 2018 Following House Committee Action.”](#)

Intellectual Property

Bob Stoll

In the copyright arena, there is interest in the Music Modernization Act and the CLASSICS Act. With strong bipartisan support in Senate, these measures are likely to pass.

As for trademarks, there are efforts to clean up the Lanham Act, enacted in 1946, but changes are not likely to pass.

In the patent space, there are high-profile Supreme Court cases to watch: *Oil States* and *SAS*. *Oil States*, which challenges the constitutionality of the Patent Trademark and Appeal Board, has the most significant potential ramifications for the industry. However, we believe the status quo will most likely be maintained, at the risk of uprooting the current appeal process. As for *SAS*,

The STRONGER Act increases efforts to level the playing field but it is not likely to pass.

We will likely see sovereignty legislation introduced to deal with issues of patent owners passing rights to Native American tribes in hopes of avoiding the PTAB.

U.S. Patent and Trademark Office Director Andrei Iancu was confirmed on 2/5/18 and he is likely to focus on: stronger IP, increased monitoring of PTAB, quality issues, controlling fee diversion away from the USPTO and narrowing the impact of patent subject matter eligibility issues as stated in the Supreme Court decisions.

Data Privacy

Katherine Armstrong

In 2017, we've noted themes such as an increasingly connected environment, privacy and security disruption and regulatory uncertainty. There are many vacancies at federal agencies and states are becoming more active, with regulations such as the New York Cyber Regulations and Illinois biometric laws. We may expect to see more cybersecurity legislation.

Companies dealing with personal data of EU residents are preparing for the General Data Protection Regulation (GDPR), set to take effect in the EU on May 25, 2018. Noncompliance with the GDPR can result in major penalties.

To account for the new year, it is important to be aware of existing and upcoming compliance obligations, to recognize that regulations are generally reactive and to deploy innovative products and services by thinking about privacy and security holistically. With privacy and security issues than ever before, it is important to avoid reputational harm and retain consumer trust.

To learn more about these issues, please visit the the Information Privacy, Security and Governance (IPSG) blog, DBR on Data at dbrondata.com. The IPSG Steering Committee, spanning multiple practice groups across

the firm, provides insights about how to best harness, manage and utilize data assets. DBR on Data covers developments in privacy, cybersecurity, information governance, data analytics, state and federal security measures and many more topics.

Telecommunications

Laura Phillips

Focus of Federal Telecommunications Regulatory Activity in 2017

- FCC Chairman Pai's stated number one priority is closing the digital divide. Programs for subsidizing rural/underserved areas and easing wireline and wireless deployments continue or are being modified. Chairman Pai's initial Section 706 review just concluded.
- Focus on new services and 5G network buildout by streamlining deployment, considering federal preemption.
- Enforcement activities in 2017 focus on black letter rule violations; the largest forfeitures in last year (\$120 and \$82 million) were reserved for serial robocall spoofers.
- Focus also on agency transparency of process, publishing draft items prior to FCC open meetings, etc.

Heat but No Light -- Net Neutrality

- In December 2017, after seeking public comment, the FCC on party lines adopted a Declaratory Ruling reclassifying broadband Internet access as an information service as opposed to a telecommunications service. Broadly speaking, this affects facilities based Internet Service Providers (ISPs).
- Most prior rules on ISPs were reversed. Remaining rules on ISPs focus on disclosure and transparency of commercial practices.
- New rules greenlight preferential access practices such as "free" Netflix for T-Mobile customers.
- The Ruling's stated intention was to promote innovation and investment, another priority of the Pai Chaimanship. Appeals have been filed.

Two Can Play at that Game

- The Congressional Review Act (CRA) was used to rescind former FCC Chairman Tom Wheeler's expansive rules on ISP privacy practices.
- Congressional concern about potentially harmful effects of deregulation is prompting Democratic efforts to use the CRA against the Pai Commission's 2017 "Restoring Internet Freedom" Declaratory Ruling. If the CRA fails and net neutrality legislation discussion heat up, look for whether ISPs or more players in the ecosystem (edge providers) are implicated.

Federal Telecommunications Legislative Activity

- Thus far communications law and policy has not been a priority for Trump administration – NTIA, which has a critical role in many spectrum allocation and other debates, had no Trump appointee at the helm for about 11 months.
- Possible rewrite of Communications Act. Issues could be: net neutrality, TCPA reform, other covered FCC reform measures and renewal of FCC spectrum auction authority.
- Communications Infrastructure also could be a part of any legislation that includes a broadband build out component.

Please visit the TCPA Blog at tcpablog.com. This blog, written by our telecommunications group members and colleagues across the firm, provides breaking news and insights about the Telephone Consumer Protection Act (TCPA). The TCPA is a federal statute that places restrictions on telemarketing calls, text messages, and faxes. It has been a source of significant class action activity in recent years, as businesses seek to navigate and creative plaintiffs' lawyers seek to exploit its many ambiguities.

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