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REGULATORY FORECAST 2015

WHAT CORPORATE COUNSEL NEED TO KNOW FOR THE COMING YEAR

STATE OF PLAY:
THE YEAR OF THE REGULATOR

CALIFORNIA:
BELLWETHER STATE

REGULATION, LITIGATION:
ACTION, REACTION

REGULATORY FORECAST 2015

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THRIVING IN AN AGE OF REGULATION

If any business is booming these days, it is the business of government regulation. Regulation is sprouting left and right, and has never had a greater impact on, nor posed a greater threat to, business communities in the United States and globally.

Founded in Washington on a platform of regulatory depth and years of experience, Crowell & Moring is alert to this trend. We are attuned to how the government interfaces with our clients' operations, how enforcers mean to do business these days, how to protect clients from the adverse exercise of agency muscle, and how to position industry to benefit from opportunities available through productive engagement with regulatory processes.

In order to better serve you, we share in these pages central insights our regulatory lawyers and consultants have gleaned, whether from their years of government service or their daily interactions with government officials worldwide, across a broad spectrum of regulated industries. With agency power at historic levels, this *Regulatory Forecast 2015* is designed, in interplay with our firm's companion *Litigation Forecast 2015*, to help you not only weather the regulatory storm but prosper from the opportunities unfolding.

Please let us know if you find this *Forecast* useful, and how we can improve it in the years ahead.

—Scott Winkelman
Partner, Member, Management Board and Executive Committee, Crowell & Moring

REGULATORY FORECAST 2015

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THE STATE OF PLAY IN 2015

THE YEAR OF THE REGULATOR

As the Obama administration takes federal power to new heights, companies brace for another year of compliance challenges

Even before the 2014 midterm elections that put the Senate in Republican control, President Obama was frustrated at having his legislative agenda blockaded on everything from immigration reform to gun control. So he declared, "I've got a pen and I've got a phone, and I can use that pen to sign executive orders and take executive actions and administrative actions that move the ball forward."

Despite expected pledges to "work together" from both the Republican leadership and the president, congressional gridlock looks to only get worse. So 2015 promises to be a year of expanding on the theme of unilateral exercise of federal power by the executive branch. In fact, not just last year, but the last few years have seen an unprecedented exercise of federal power through the issuance of new regulations, the reinterpretation of existing ones, and the enforcement of both, as well as more novel regulatory approaches. The trend shows through in virtually every industry and regulatory area examined in this book, and it looks likely to continue through 2015 and beyond.

The Obama administration is proud of this assertive stance, pointing to progress even in the face of what it calls a "do-nothing" Congress. By contrast, congressional Republicans—and some constitutional scholars—have accused the administration of regulatory overreaching. But one thing seems certain about this new wave of administrative activism: it spells new headaches for business.

More regulation means more compliance costs and challenges. More aggressive enforcement means harsher penalties

Wm. Randolph Smith, Thomas Means, and Elliott Laws

and more intrusive sanctions for failure to comply. And more key decisions being made by the executive branch—rather than by Congress or the courts—means businesses have to be even more focused and strategic to make their views known and influence the outcomes.

"We're going to see an executive branch that is increasingly willing to take action through regulation and enforcement power, so businesses must be prepared to react differently," says Wm. Randolph "Randy" Smith, chair of the Antitrust Group at Crowell & Moring. "Executive power is increasingly being wielded with limited, if any, constraints from the legislative or judicial branches."

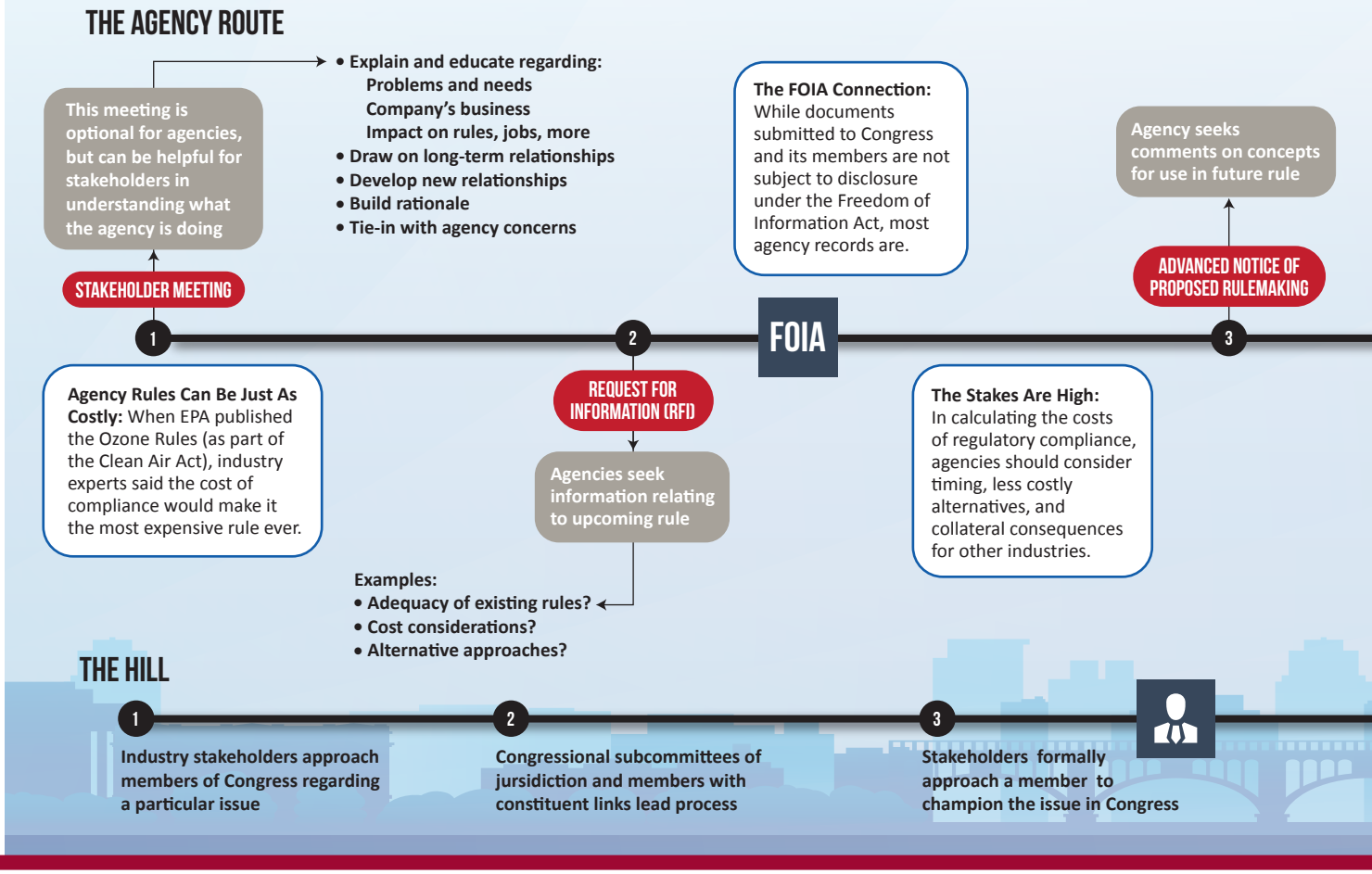
"This is not how government operated in the past," adds Thomas C. "Tim" Means, chair of the Administrative Law and Regulatory Practice at Crowell & Moring. "The federal branch is grabbing all of the levers, every tool at its disposal, to achieve its policy objectives. If you support those policies, it seems great. But for businesses, this new use of executive power is unprecedented. It's a real curveball, and they're struggling to understand the new regulatory paradigms."

COUNTING THE COST

What might have been the president's most substantial policy achievement last year never got a hearing in Congress. It was the Environmental Protection Agency's (EPA) proposed rules to cut carbon pollution from power plants. President Obama's aggressive stance on the environment may have the biggest impact on business of any policy area. The U.S. Chamber of Commerce claims the new carbon emissions regulations alone

NAVIGATING WASHINGTON

AGENCIES WILL BE WHERE THE ACTION IS IN 2015



will cost the economy an average of $51 billion each year through 2030.

In fact, President Obama has issued fewer executive orders than his two most recent predecessors, according to the American Presidency Project at the University of California at Santa Barbara. But critics and admirers alike cite his willingness to make extensive use of interpretive memoranda and more creative administrative approaches to regulation that have made big impacts in areas including labor and employment, financial services, immigration, health care, consumer protection, and others to be described in this *Forecast*.

Some of these actions fly under the radar of the popular press. A typical example is the slew of "fair pay" orders and memoranda imposing new obligations on federal contractors issued last year. Though they received relatively little attention, these actions will have a big impact on business: The Department of Labor estimates that 24,000 companies have federal contracts, employing about 28 million workers. (See Government Contracts, page 26.)

"There's a furious debate about the potential cost of all these new regulations on business," says Smith. "But there is no doubt that companies need to budget and plan for compliance."

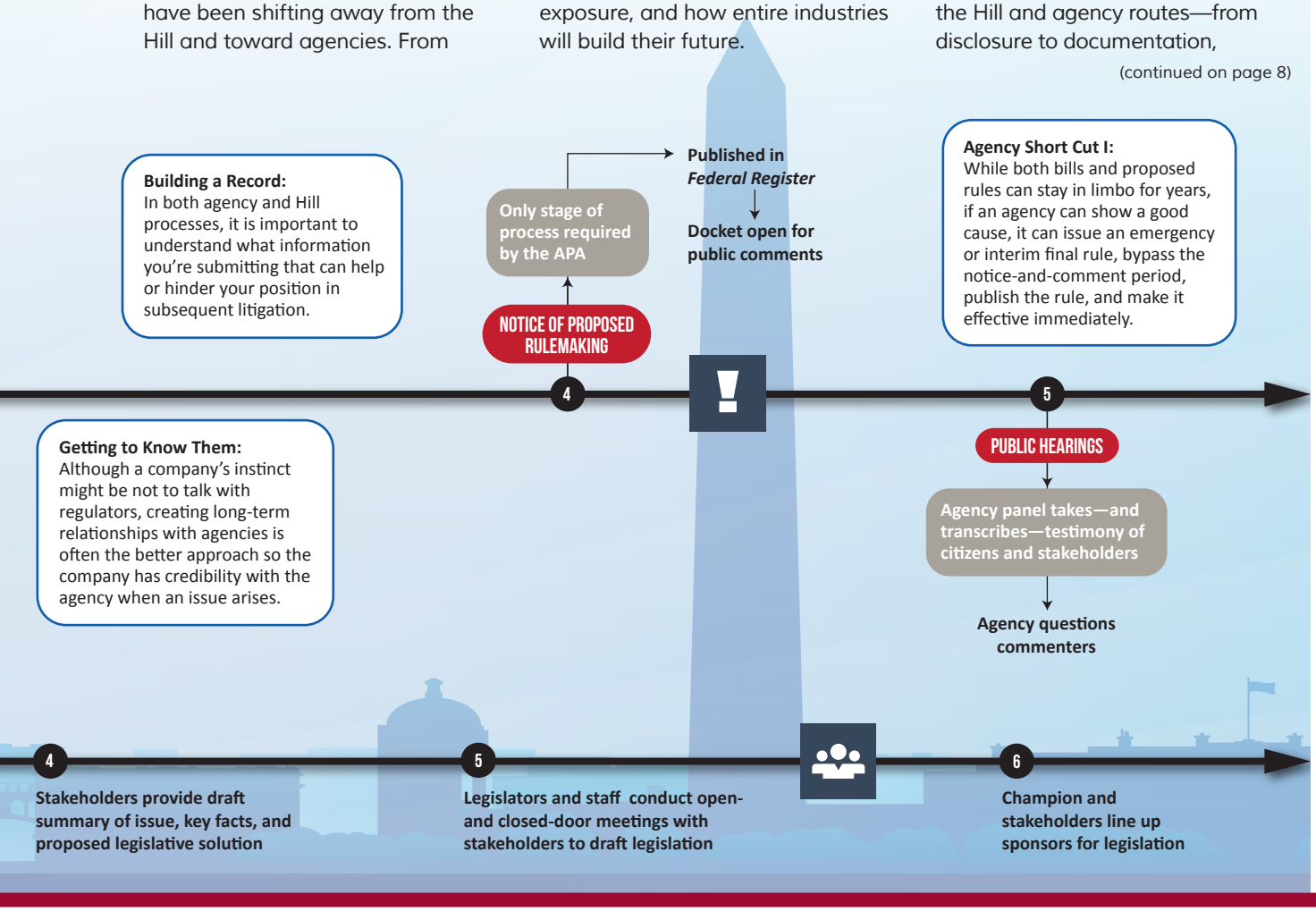
GOING IT ALONE

The president's orders and actions have been crafted "almost entirely behind closed doors," *The New York Times* noted in an analysis last August. White House officials held dozens of "listening sessions" in 2014 as they formulated policy in a variety of areas. While businesses and business groups were invited to some of these sessions, they were not public hearings, with public debates and invitations for comment.

This year, agencies are filling the policymaking gap left by Congress. Underscoring that trend, government relations strategies for both trade associations and industry players have been shifting away from the Hill and toward agencies. From greenhouse gas to health care regulation, it is the agencies, more than the Hill, that are initiating regulatory actions that significantly impact the bottom line, litigation exposure, and how entire industries will build their future.

The charts below and on the following pages show the not-so parallel routes of the agency rulemaking and legislative processes. The key points of difference between the Hill and agency routes—from disclosure to documentation,

(continued on page 8)



As the *Times* noted, "The go-it-alone approach has left the administration—which claims to be the most transparent in United States history—essentially making policy from the White House, replacing congressional hearings and floor debates with closed meetings for invited constituencies."

This approach has attracted criticism even from allies. George Washington University law professor Jonathan Turley—who has said his politics generally align with the president's—recently testified that Obama has continued President George W. Bush's practice of "issuing signing statements that 'interpreted' statutes in ways that effectively amended or negated provisions." But Obama has gone further, Turley says, by barring enforcement of rules by agencies (such as provisions of the Affordable Care Act) for political reasons. Such practices amount to "legislation by executive fiat," he said, which "further invest the Administrative State with a degree of insularity and independence that poses an obvious danger to liberty interests protected by divided government."

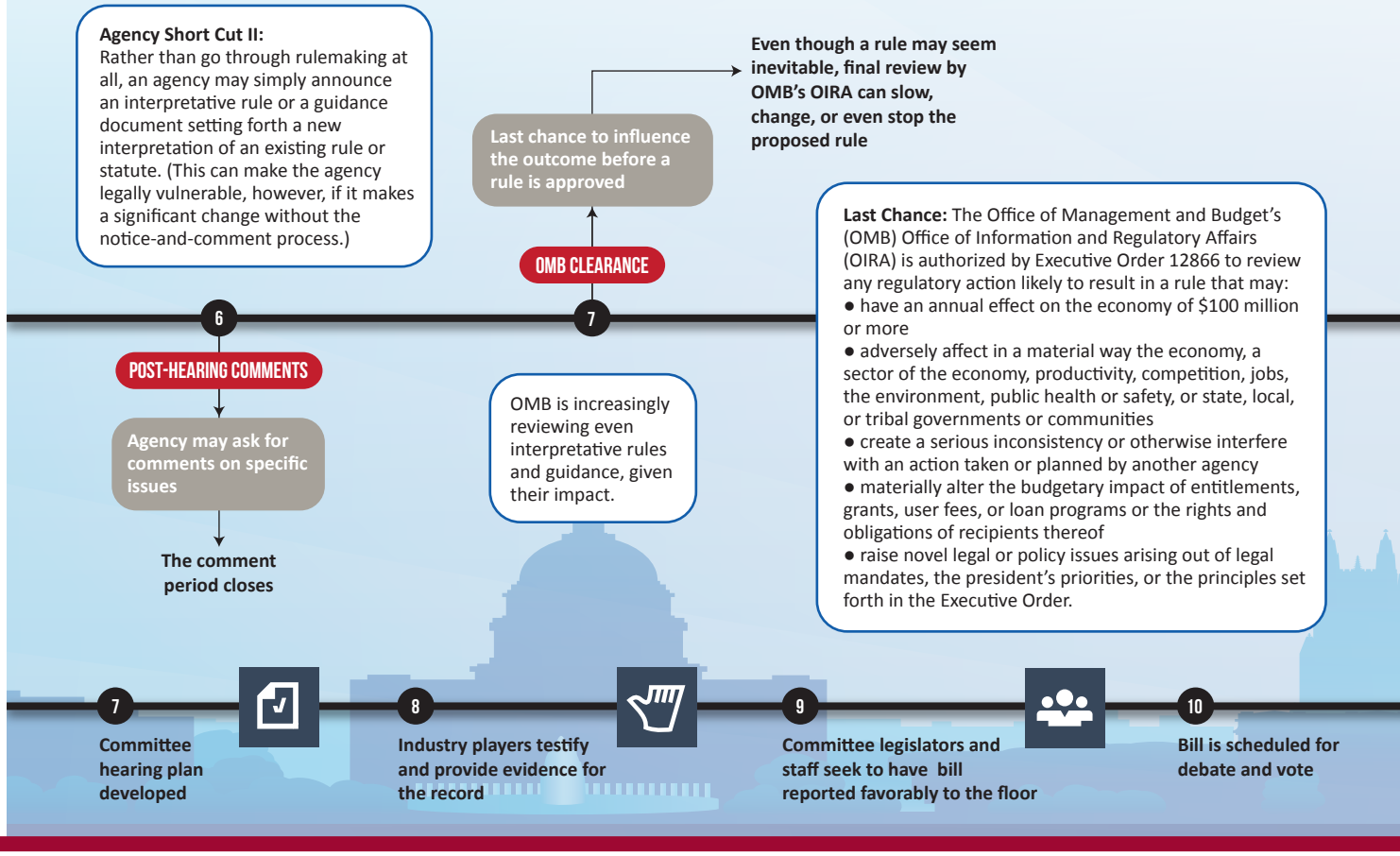
TESTING LIMITS

Encouraged by an activist White House, federal agencies have also been testing the limits of their statutory authority, notes Elliott Laws, a partner in Crowell & Moring's Government Affairs and Environment & Natural Resources groups and a former EPA official. Like the president, agency leaders also see themselves as taking up a baton that Congress has dropped. For example, "no major environmental statute has undergone a major reauthorization since the 1990s," Laws notes. In the meantime, new environmental challenges—greenhouse gases, new findings about substance toxicity, and the like—have emerged. In some cases, there is broad agreement—among

THE STATE OF PLAY IN 2015

from the critical role played by the Office of Management and Budget (OMB) to ways in which outcomes can be challenged, are detailed in the boxes on either side of the agency timeline.

One key difference between the Hill and agency routes is the point at which discussions with policymakers become part of the public record. On the Hill, interested parties may share their views with decision makers both on and off the record. At agencies, however, once the rulemaking process officially begins, meetings with rulemakers are reported publicly and officials must



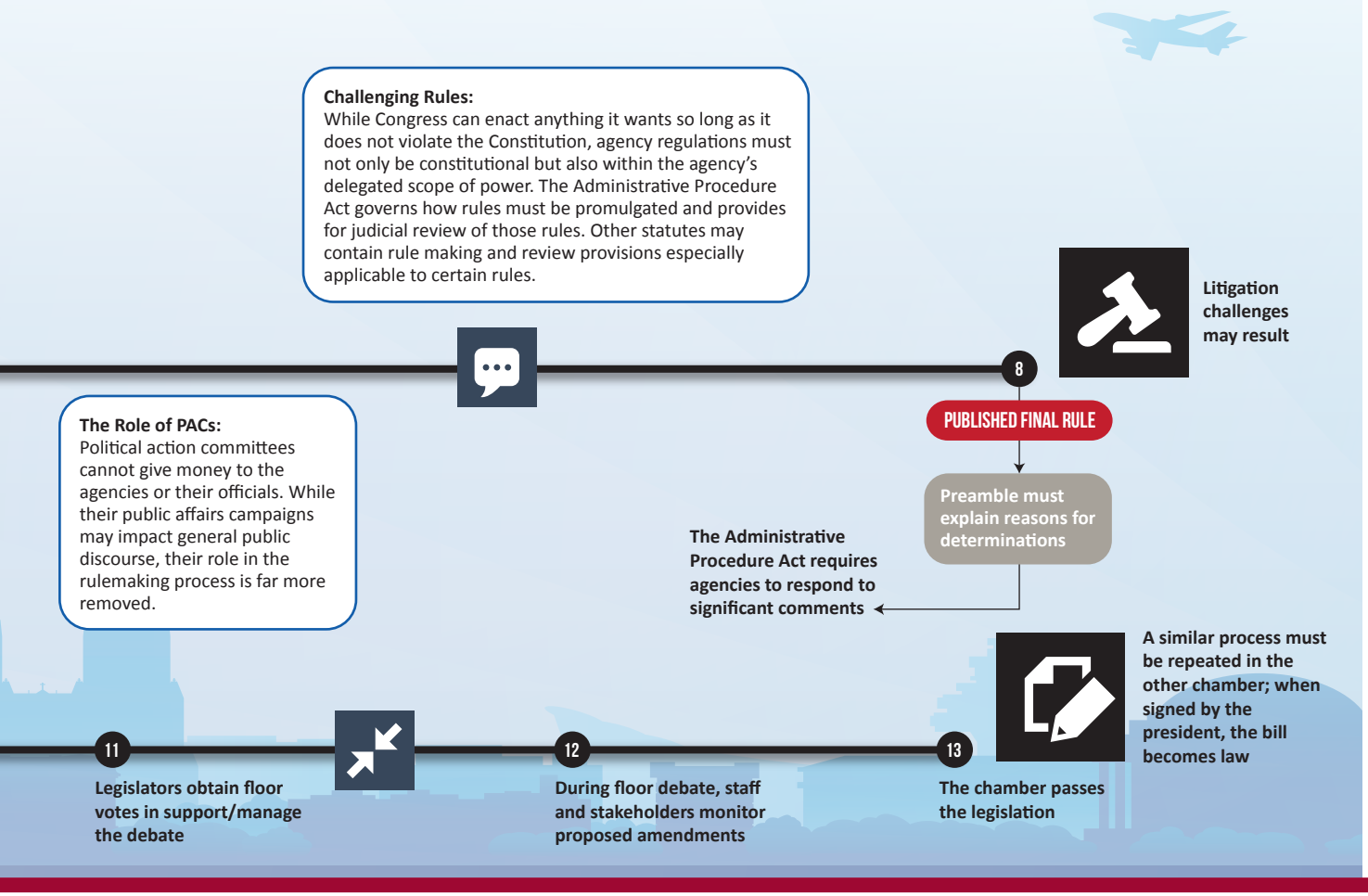
stakeholders, if not in Congress—that revisions are needed because the laws as currently written cannot be interpreted to address these newer concerns. (See Chemical Regulation and Cybersecurity, page 42, for a further discussion regarding the reform of the Toxic Substances Control Act.)

In the absence of clear congressional direction, agencies are finding new ways to regulate. But in doing so, they have been accused of effectively colluding with favored interest groups when setting their priorities. In a tactic known as "sue-and-settle," an interest group sues an agency claiming that agency is not enforcing the law. As part of a legal settlement (developed behind closed doors), the agency makes promises, such as agreeing to write new regulations. While there may be public comments on either the draft settlement or the resulting proposed rules, it may well be too little, too late, Means says: "The die is cast. Those rules are rarely changed as a result of public comment. Sue-and-settle provides interest groups a fast track to expand an agency's power and reach, and to promulgate rules that they wanted—and that the agency may have wanted as well."

Sue-and-settle tactics are most frequently employed by environmental groups. As a former EPA official, Laws helped the EPA implement extremely complicated rules under tight resource constraints. Sue-and-settle allows the interest groups to greatly influence the agency's agenda, Laws says. "The agency must focus on complying with court-ordered schedules rather than the priorities that the agency or the administration would have preferred to make. They greatly reduce the agency's ability to prioritize," he explains.

Affected industry is not entirely powerless in the face of such tactics. Indeed, Means has successfully challenged sue-and-settle tactics on a number of occasions. And companies

produce memos about discussion topics. The rulemaking process relies more on docketed written comments and public forums. While some may prefer the transparency this process offers, it can have a chilling effect on candid discourse. For companies that may lose jobs, stock price, and business to the competition, candor in the comment process can wreak havoc on a bottom line and subject corporate management to litigation. In fact, public companies have even faced litigation as a result of public comment about the expected impact of a proposed agency rule.



are free themselves to etition agencies to take specific actions or interpretations, Laws says.

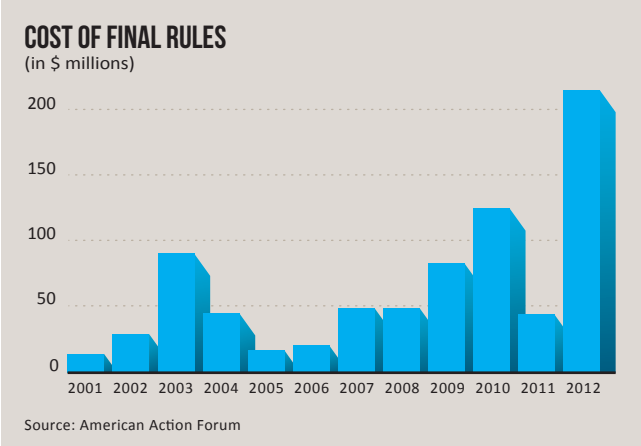
THE ENFORCERS

As the number and scope of administrative rules multiply, so do the penalties for failing to comply. If just measured in fines alone, these penalties are rising fast: more than $13 billion in 2014, up from about $7 billion in 2013, according to economist Brandon Garrett at the University of Virginia. (In 2008, the figure was closer to $2 billion.) And, in the realm of consumer protection, for example, the Federal Trade Commission has been increasingly willing to go to court to seek monetary damages or consumer redress rather than settling for an injunction, says Smith.

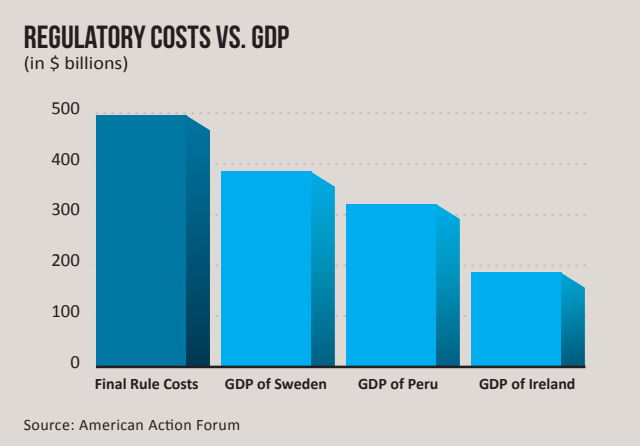
But enforcement actions are increasingly resulting in much more than a fine and an order to stop the violations. Prosecutors are demanding deep and very specific changes in management and embedding monitors in the company to ensure that they occur. (For more details, see White Collar, page 34.) Settlements are requiring corporate policy changes, staff training, remedial community training programs, and more.

In a typical example, in the aftermath of a tragic 2010 mining accident, the mine operator paid $209 million. In addition to fines and restitution to victims, the 2011 settlement included $80 million for mine safety improvements in all the company's mines and $48 million for a "mine health and safety research trust," as well as a commitment to self-report violations and to apprise regulators of progress toward further safety improvements.

In addition, companies facing even the threat of enforcement actions have allowed regulators to influence their



The cost of final rules published in the *Federal Register* has moved up in fits and starts.



The cumulative cost of U.S. regulations passed in 2009-13 dwarfs that of some countries' GDPs.

policies in new ways. For example, after a safety crisis, General Motors signed an accord with the National Highway Traffic Safety Administration in which it agreed to "implement training policies that 'expressly disavow statements diluting the safety message' in internal communications," according to an article in *Law360*. The move is part of a growing trend of agencies trying to "shake up the company culture they attribute the safety crisis to," the article reports.

In another case, the Consumer Product Safety Commission is convincing retailers to pull products from their shelves when it cannot convince manufacturers to recall them. Retailers are increasingly willing to go along, now that the commission's civil penalty cap has increased from $1.8 million to $15 million.

Regulators are also becoming more aggressive in their efforts to root out alleged misdeeds, largely through efforts to recruit insiders. For example, in 2013 the government enhanced whistleblower protections for employees of government contractors and extended the protections to subcontractors. When coupled with significant awards afforded to whistleblowers, the protections amount to "deputizing the workers of America to blow the whistle on their employers and act as a partner in enforcement," says Means.

OUR FORECAST

The recent regulatory expansionism will continue through 2015—and likely beyond—thanks to a striking confluence of events.

First, the third year of a president's term tends to be the most aggressive in terms of policymaking, notes Means. Midterm elections are over, political appointees are firmly in place, and the administration is acting with its legacy in mind. By contrast, in 2016, the administration may face pressure to pull back on rulemaking for the sake of pre-election politics or transitional smoothing.

Second, the 2013 decision by Democrats to strip Republicans' ability to filibuster the president's nominees has resulted, for the first time in a decade, in a federal appeals bench—including the all-important D.C. Circuit—in which judges appointed by Democrats considerably outnumber Republicans. These judges may be more likely to favor the administration in legal challenges to the administration's authority.

Third, a Supreme Court ruling in 2013, *City of Arlington v. FCC*, appears to give agencies wide discretion in deciding the scope of their own statutory authority. *Arlington* continues a tendency running back 30 years for courts to defer to agencies when there is ambiguity about whether the agency is allowed to act under its authority established by Congress. As a result, unless Congress clearly mandates otherwise, agencies can expand their authority as far as they see fit. And since their statutory authority tends to be quite broadly stated, agencies have a lot of leeway. (For political factors that might affect the regulatory climate in 2015, see, "Did the Midterms Matter?" p. 11.)

GET OUT YOUR CHECKBOOK

The most immediate impact of all the federal activism on industry is an increase in compliance costs. The American Action Forum, a think tank, says that in the first nine months

of 2014 alone, the federal government had proposed or finalized rules imposing $150 billion in compliance costs and had imposed 30 million hours in paperwork on American companies. That's up from $112 billion for all of 2013. (The largest costs—by far—are imposed by rules related to energy and the environment. Food and drugs are a distant third.)

The administration's approach to governing has created a cloud of uncertainty for companies trying to plan and budget for compliance, notes Means. While agencies are being given tremendous leeway on drafting and interpreting rules, many of the new rules will almost certainly face legal challenges. That's because agencies are vulnerable to accusations that they have overstepped their statutory authority, Laws says. "Companies are left with questions like: Which rules will survive legal challenges? How will the agencies interpret the rules? And how might their interpretations change, with or without rulemaking?" Means adds.

The picture gets even cloudier when politics are thrown in. What will happen to this wave of regulation, for example, if Republicans take the presidency in 2016? Will they suspend or repeal regulations, and which ones? Will the next president—from whichever party—voluntarily relinquish power the Obama administration claimed, or will he or she retain or even grow it?

Another concern for companies: the impact of gridlock and federal government-bashing on the federal workforce. "Already, about a third of federal workers are eligible for retirement," notes Laws. "The exodus will accelerate as employee morale plummets in the face of constant congressional investigations, criticism, and budget cuts." Highly regulated companies may have hundreds or even thousands of weekly contacts with their federal regulators, usually for routine operating, permitting, and approval issues. "As experienced personnel depart, these activities will face delays. To take just one example, estimates for a major capital improvement could be off by months if an experienced agency permit writer retires and isn't replaced, or is replaced by someone unfamiliar with the company's operations. In this respect, the gridlock between Congress and the president has a more granular impact on a company than Washington's policy debates," Laws says.

STRATEGIES FOR 2015

For businesses hoping to have an influence on the course of regulation, much of the action has moved from Congress to the executive branch. "It's more important than ever to build and sustain relationships with agencies that could affect your business," says Laws. "That means interacting with them regularly and educating them about issues important to your industry. You want to build your reputation and your comfort level with them well before any sensitive issues come up, such as potential enforcement actions or proposed regulations you want to fight."

Companies struggling with compliance do have a range of options, Means suggests. "As they devise their compliance strategy, companies may want to seek guidance from agencies on how their rules might apply to them; seek waivers, exceptions, and mitigating guidelines; and develop sound policy reasons to have the agency construe its rules in a manner that achieves the regulatory goal but is less onerous for a company," he explains.

Congress still has a role to play in affecting a company's regulatory burden. For one, a legislator can write letters or hold hearings in an attempt to influence agencies on important issues. And legislative wins are still possible for companies that can find issues that can be trumpeted by both sides of the aisle as job creators. As in the case of agency leaders, it's important for companies to establish ongoing relationships with relevant members of Congress, rather than reaching out only when they need something from them.

In short, 2015 looks to be a banner year for regulation and enforcement. Businesses will need to work harder than ever to prepare for new executive actions, comply with existing ones, and make their views known.

DID THE MIDTERMS MATTER?

Now that they control both houses of the legislature, what chances do Republicans have of putting the Obama administration's aggressiveness in check?

The short answer is, not a great deal. Republicans still lack the two-thirds majority needed to override a presidential veto. As a result, gridlock almost certainly will persist in Congress, giving the administration a comparatively free hand.

Yet Congress still has some tools at its disposal. A fully Republican legislature can and might:

- Continue oversight of the administration via hearings and investigations.
- Slow down or block appointments, impairing agencies' ability to act or stemming the growth of the president's new judicial majority.
- Use the power of the purse. For example, Congress might extract concessions from the White House in exchange for agreements to keep the doors of government open. Or Republicans might insert riders into continuing budget resolutions that foil the administration's spending plans.

While 2015 might hold political surprises, one thing is likely: after a period of "feeling out" the other side and its willingness to compromise, both the Obama administration and Congress will barrel ahead with their respective agendas.

ACTION AND REACTION

The growing interplay between litigation and regulation

Cheryl Falvey

It's no secret the current administration has been more focused on regulation than have some earlier administrations. That's not just driving new rulemaking. It's also resulting in more stringent regulatory enforcement and follow-on litigation—essentially, new rules governing corporate decision making from courts and administrative decisions as well.

"For regulations that have already been implemented, agencies will increasingly look for violations and drive compliance through more rigorous enforcement. Whether automobiles, food, or consumer products, the regulatory enforcement action with respect to one company sends a message across multiple industries as companies move toward more rigorous compliance programs," says Cheryl A. Falvey, co-chair of Crowell & Moring's Advertising & Product Risk Management Group and former general counsel of the Consumer Product Safety Commission (CPSC). "Litigation is picking up where regulation leaves off. The plaintiffs' bar is aggressively filling in the gaps with class action litigation in areas where the regulators have declined to act."

That has implications for both litigators and regulatory counsel. Both groups will need to pay attention to new regulations, new interpretations of existing regulations, and increased enforcement. They'll also need to be aware of consumer concerns, which even if they don't result in new regulation will drive litigation. To respond effectively, litigators and regulatory counsel will need to collaborate and ensure their organizations have robust compliance programs.

The intersection of regulation and litigation will play out across a broad range of industries. A good example is in the energy sector, where shipping oil by rail is becoming more controversial as it becomes more common. The issue rose to prominence following multiple safety incidents—most notably the Lac-Mégantic derailment in July 2013, in

INJUNCTION AS REGULATION

COMPANY	SETTLEMENT	INJUNCTIVE TERMS
BEAR NAKED	$325K fund, $0.50 refund per product purchased	Remove "100% Natural"
TRADER JOE'S	$3.375M fund, minus attorney fees	Remove "All Natural" and "100% Natural"
BARBARA'S BAKERY	$4M fund, up to $100 refund per customer	Modify labels, remove GMO ingredients, participate in Non-GMO Project
KASHI	$5M fund; $0.50 refund per product purchased, up to $1.25M in attorney fees	Remove "All Natural" and "Nothing Artificial"
NAKED JUICE	$9M fund, includes up to $3.12M in fees	Remove "All Natural" and test "Non-GMO" claims

In recent food industry settlements, injunctive terms required companies to alter their behaviors.

which 47 people were killed.

The Pipeline and Hazardous Materials Safety Administration has proposed tightening oil train and tank-car requirements. That could affect aspects such as train speed and tank-car design. "That rulemaking will wend its way through the regulatory process," Falvey explains. "But in the meantime litigation moves forward over the same issues."

States such as Minnesota and New Hampshire have already moved to strengthen their oil-by-rail safety training and emergency response programs. Maine, California, and other states have raised questions over local versus federal jurisdiction. And in New York and California, environmental groups have brought litigation against relevant government agencies.

CONSUMER CONTROL

Consumer groups will also gain influence, whether by lobbying for tougher regulations and stricter enforcement, or through litigation. "Consumers are increasingly concerned about safety and product ingredients," Falvey points out. "That will most directly affect sectors such as food, consumer products, and chemicals, but it has implications for any industry."

Neither the Federal Trade Commission (FTC) nor the Food and Drug Administration (FDA) has regulated terms like "organic" and "all-natural." But that hasn't stopped states like California from addressing these issues in the courts. Several recent cases have resulted in large settlements, as well as injunctive terms that prohibit companies from using phrases like "nothing artificial" and "non-GMO," referring to genetically modified organisms.

"We'll see similar issues around consumer privacy," Falvey predicts. Data privacy has long been regulated in health care and financial services. But as consumers watch the growing use of personal data and interactive technologies in other industries, they'll demand greater protections—through either regulation or the courts. "As we see headlines about data breaches at major retailers, there will be greater interplay of regulation and litigation around security measures," Falvey says. "The actions by the FTC and courts then define the developing standard of care required for security of devices that access the Internet in a way that reveals information consumers may expect to remain private."

Even where there are no new regulations, injunctive terms driven by regulatory enforcement and consumer action will function like regulations. In several California food-industry cases, injunctive terms require companies to test products for the presence of GMOs and participate in GMO-verification programs. "That's the equivalent of being regulated," Falvey notes, "and it's something we'll see more of." (See Food, page 40.)

RENEWED COMPLIANCE FOCUS

In response, companies should renew their focus on regulatory compliance, Falvey says. "The best way to avoid enforcement problems and mitigate the risk of litigation is to ensure the entire enterprise is fully engaged in compliance," she recommends.

That requires executive commitment, dedication of resources, adequate communication and training, and "implementation of tools that promote compliance," Falvey says. Such tools could be simple measures such as check boxes at key steps in company processes to ensure the right business owners take the right actions. And the value of regular and close communication with the regulatory agency cannot be overstated.

Just as important, litigators and regulatory counsel must increasingly collaborate. Why? "You need to anticipate litigation that might arise from regulatory decisions," Falvey says. For example, a product recall that satisfies the FTC, FDA, or CPSC could still result in a class-action lawsuit, and the superiority of the federal recall process may defeat class certification."

"You need to respond to the demands of regulators, but you simultaneously have to consider your class-action exposure," Falvey concludes. "The more litigators and regulatory counsel work together, the greater the chance you'll avoid both regulatory sanctions and significant litigation liability exposure."

THE INTERPLAY OF SOCIAL MEDIA

Social media is a key factor in the intersection of regulation and litigation. "Social media can almost overnight have a profound effect on a company's brand and valuation," says Crowell & Moring partner Cheryl A. Falvey.

A cautionary tale involves Procter & Gamble's Pampers Dry Max diapers. After the product hit the market in mid-2010, the CPSC received thousands of complaints about diaper rash. Testing by P&G and the CPSC found no product flaws. But that didn't stop consumers from taking to social media.

P&G was no stranger to social-media communications. But the company's efforts to counter the diaper-rash rumors backfired with consumers. P&G settled a class-action lawsuit brought by 59 parents, agreeing to pay each $1,000 per child, pay $2.73 million in legal fees, and fund medical education on diaper rash. (The settlement was overturned in 2013 on the grounds that it undercompensated the class members while overcompensating their counsel.)

P&G learned that engaging unbiased opinion leaders offered a better solution than challenging allegations in the social-media rumor mill, according to *Attack of the Customers*, by Paul Gillin. "You can't join a community at a time of crisis," the book quotes Paul Fox, P&G's director of corporate communications, saying, "You have to already be invested."

CALIFORNIA: AT THE VANGUARD OF REGULATION

When California sneezes, does the country catch a cold? Some of the nation's most sweeping regulatory changes got their start in the Golden State. In 2015, looking ahead means looking west, where energy and health care top the regulatory agenda.

Nancy Saracino and Frank Lindh

Electricity generation is always top of mind in California, and in 2015 it will be no different. California isn't an island, but it's unique in its degree of energy independence, given its size and concentration of population along the coast and inland valleys.

As a result, "California officials are accustomed to choosing where to locate power plants and which energy sources to use for generation," says Frank R. Lindh, a partner in Crowell & Moring's Energy Group and former general counsel of the California Public Utilities Commission (PUC). But as the Federal Energy Regulatory Commission (FERC) looks to ensure reliability in the West, it also wants a say.

In response, California is pursuing an innovative solution. The state's independent system operator (ISO) and PUC have established a framework for balancing oversight. If adopted by the PUC, the framework will preserve for the PUC the primary role of overseeing contracting for new capacity. Where there are gaps, the ISO will have authority to procure power to meet demand in specific areas.

"This framework avoided what could have been lengthy and contentious litigation between state and federal authorities," Lindh says, something that has plagued other regions. "The California framework should be a welcome development for power-plant developers, because it sets clear rules, roles, and stability."

LAYING UP ENERGY

As California pursues more wind and solar power, it faces the challenge of ensuring capacity when the wind isn't blowing or the sun isn't shining. One answer is energy storage on an unprecedented scale. Prompted by state legislation, in 2013 the PUC adopted rules requiring utilities to procure hundreds of megawatts of storage. Numerous storage technologies are in development, including lithium-based batteries and compressed air.

"We are seeing a land rush for energy-storage capacity," Lindh predicts. "This could revolutionize the energy industry, and it means tremendous opportunities for entrepreneurs who develop viable technologies."

But there remain some engineering issues to work out, says Nancy Saracino, a partner in Crowell & Moring's Energy Group and former general counsel of the California ISO. "There will need to be technical studies and new rules related to how these storage resources connect to the grid, help with grid reliability, and charge," she says.

Energy storage will help drive California's push toward micro-grids—geographically isolated energy infrastructures, often powered by more distributed, less centralized generation. "Watch this space," says Lindh. "The micro-grid will come of age in 2015-2016," he predicts.

ENERGY IN THE BALANCE

Among the most dynamic energy developments in California is the establishment of an energy imbalance market (EIM). The western grid is managed by 38 balancing authorities, each responsible for syncing supply and demand in its region. Dramatic growth in wind and solar means energy supplies can vary hour by hour, straining the system. An EIM automatically dispatches resources across balancing authorities in real time.

The California ISO has implemented the first western EIM, with PacifiCorp's two balancing authorities as the initial participants. The market went live in November 2014, synchronizing systems across eight western states.

"This is major," Saracino says. "It's an opportunity that balancing authorities in other regions will want to consider."

Saracino also emphasizes that the EPA's proposed Clean Power Plan, under Section 111(d) of the Clean Air Act, will require states to work more collaboratively. "The EIM is a good first step," she says.

HEALTH CARE CONSCIOUS

As with energy, California has been among the most innovative states in health care, particularly in adapting to the Affordable Care Act (ACA). Most provisions of the ACA went into effect by January 1, 2014. In 2015, the focus will be on implementation. And California's experiments and experiences have implications for the rest of the country.

One example is Cal MediConnect, a three-year pilot by the state's Department of Health Care Services (DHCS) and the federal Centers for Medicare & Medicaid Service. The program will coordinate care for the 1 million "dual eligibles" covered under Medicare and Medi-Cal with the goal of providing better overall care. Eligible individuals must enroll in a managed-care plan unless they specifically opt out. This comes on the heels of DHCS's shift to provide all Medi-Cal services in a managed care environment via contracts with private health plans.

The implementation of health care exchanges and the expansion of Medicaid have raised issues for health plans, providers, and regulators alike. "California regulators are looking at whether health plans have adequate provider networks to meet the needs of people who have enrolled in their products," says Kevin B. Kroeker, a partner in Crowell & Moring's Health Care Group. Network adequacy can be particularly challenging in California, with providers reluctant to contract in some rural areas.

Providers have their own concerns. If they're excluded from a health plan network, they may no longer have access to patients they otherwise could serve. "In some states, providers have been suing insurers based upon exclusion from networks," Kroeker says. "In California, some providers aren't certain whether they're in a network, and this has caused confusion for both providers and members." With recent concerns over the networks for the California exchange, legislation was passed requiring health plan regulators to annually review each health plan network. "This is potentially a big increase in workload

VIEW FROM WYOMING: WIND AND WILDLIFE

California is the nation's most populous state, with 38 million residents and tremendous energy demand, especially for renewables. Wyoming is the country's least populous, with 583,000 residents—fewer than Washington, D.C. But Wyoming also boasts the nation's greatest wind resources.

"There's tremendous opportunity for Wyoming to help California meet its aggressive goals for renewable energy," says Dave Freudenthal, former governor of Wyoming and senior counsel at Crowell & Moring. "The challenge will be overcoming the technical and regulatory hurdles of transporting that energy more than 1,000 miles."

That won't be the only regulatory hurdle for western states like Wyoming. "The public-lands states face unique regulatory challenges," Freudenthal explains. "For example, the Department of the Interior is charging additional fees for oil- and gas-well permits, and that revenue will fund more inspections and regulatory enforcement."

In addition, there will be increasing intersection of energy and endangered-species regulation. "One example is that the greater sage-grouse bird could be listed as 'threatened' in September 2015," Freudenthal notes. "That alone would affect 11 of the largest-producing oil and gas states." Significant impacts on Western wind projects can also be expected.

Gov. Dave Freudenthal

both for the health plans and their regulators," says Gary L. Baldwin, a counsel in Crowell & Moring's Health Care Group.

Health plans will increasingly emphasize financial arrangements whereby providers will be expected to take on financial risk, including global risk for the end-to-end services provided to plan members. Many California providers have embraced this approach by obtaining special licenses that authorize the assumption of global risk. "The big challenge for providers that move to the regulated world of global risk is recognizing that they are in a heavily regulated industry, which requires them to maintain financial reserves and manage continuous scrutiny by the regulator," says Baldwin.

As Kroeker points out, "Coordinated care in which providers work collaboratively is what's intended under the ACA. In many cases, such implications of the ACA will play out first in California." In addition, California-based insurers and providers are helping to spread these trends across the nation.

Because of its large size, population, and economy, as well as its typically progressive stance, California will remain at the vanguard of regulation in 2015. Concludes Saracino, "Especially in the most active arenas like energy and health care, the rest of the country would be wise to watch how regulatory issues play out in California."

Kevin Kroeker (left) and Gary Baldwin (right)

Kyle Parker

VIEW FROM ALASKA: PRECEDENT-SETTING

While California is concerned with electricity generation and renewables, Alaska remains firmly focused on oil and gas exploration and development—even as the state has fallen behind California as an oil producer.

State and federal submerged lands in the Arctic Ocean are believed to contain many tens of billions of barrels of recoverable oil, according to the U.S. Geological Survey, enough to sustain production for decades. Projections for natural gas in the Alaska Arctic exceed 224 trillion cubic feet, which positions Alaska to be a key supplier to markets in Asia.

To date, most oil and gas exploration and development activities in Alaska have taken place on state lands. Companies have been expanding their operations on federal lands in recent years. "It is widely anticipated that the next major oil discovery in Alaska will happen on federal submerged lands in the Arctic Ocean," says Kyle W. Parker, a Crowell & Moring partner who heads the firm's Anchorage office. However, any future development activities on offshore lands in the Arctic will face significant regulatory hurdles, Parker says.

In fact, like California, Alaska will be a bellwether for energy regulation across the nation. "Oil and gas projects in Alaska are subject to tremendous scrutiny from environmental groups and the courts," Parker points out. That level of regulatory oversight and public scrutiny will extend to other regions.

EUROPE: TOP TRENDS IN COMPLIANCE

The EU will be firing on all cylinders

Kristof Roox and Salomé Cisnal de Ugarte

After a slowdown last year due to leadership transition, the European Union (EU) regulatory juggernaut is expected to charge full steam ahead this year with new developments and initiatives in all areas, particularly in data protection, food, antitrust, banking, and sanctions. As always, compliance with European standards will pose a challenge to U.S. companies, notes Kristof Roox, a partner in Crowell & Moring's Intellectual Property Group and head of the firm's Brussels office, which focuses on EU antitrust, trade, and regulation, as well as Belgian law. While the EU's *regulations* are applied the same way throughout the union, its *directives* must be transposed into national legislation and may be implemented differently in each country. "It's not good for coherency and transparency, and it can be a nightmare for compliance," Roox says.

Here are some of the areas that should see important developments in 2015:

DATA PROTECTION The EU's data protection directive dates to 1995, when the Internet was just gaining traction, and was implemented differently in different member states. The General Data Protection Regulation, proposed in 2012, will replace the 1995 directive and will likely be adopted in 2015. As a regulation, it will strengthen and unify data protection within the region as it will have a direct effect in all EU member states. Crucially for U.S. companies, the current draft of the new regulation says it will apply to organizations no matter where they are based, as long as they process personal data of EU "data subjects" when offering goods or services or monitor data subjects' behavior, for example by installing "cookies" on their computers. Failure to comply with the regulation can lead to fines up to 100 million euros or up to 5 percent of annual worldwide turnover (i.e., net sales), according to the current draft. If the regulation is passed in 2015, companies will have to be fully compliant by 2017. "Companies will need to act soon, as data processing practices in global operations are not changed overnight," says Roox.

ANTITRUST Here again, the rules and penalties are tightening, says Salomé Cisnal de Ugarte, a partner in Crowell & Moring's Antitrust and International Trade Groups:

- A new directive will require every EU state to allow companies and individuals hurt by antitrust violations to sue for damages.
- The European Commission is considering extending its review to deals involving the acquisition of non-controlling minority shareholdings.
- As a result of a modernization effort, regulators have streamlined the rules for review of deals in which companies receive government assistance, and will intensify the scrutiny over member states' tax dealings with multinational companies, known in Europe as EU state aid control.

FOOD Last year, companies worldwide scrambled to prepare for the new food labeling requirements that came into effect on the first of this year. (But the preparations are not over—the nutrition labeling mandate does not take effect until the end of 2016.) Now the EU is taking a close look at foods for specific populations like infants or foods used for medical purposes.

CHEMICALS By September 1, companies that produce "biocides" must get on the list of "active substance suppliers" with the European Chemicals Agency or their products must be taken off the market. A biocide is a pesticide or antimicrobial agent that is not used for agriculture. Since biocides are widely used in industry and medicine, this new regulation stands to affect thousands of companies, Roox says.

U.S. companies are wise to watch these and other developments in the EU for their potential impact domestically. The EU often inspires new rules and even new litigation challenges that play out in the U.S. "For many industries, regulation happens first in the EU," says Roox. "You can look at Brussels for a sense of what will happen next."

THE DRONES ARE COMING—EVENTUALLY

While a small number of businesses can use them, the rest may face a long wait

Gerry Murphy

Until recently, when most Americans heard "drone," they thought of unmanned aircraft doing surveillance or military strikes in the Middle East. But American companies are eager to beat these military tools into profit-driving ploughshares. What were once seen as "hobby" aircraft have also become incredibly sophisticated. Some enterprising businesses have already used drones (also known as unmanned aircraft systems, or UAS) to gather news, monitor crops, take dramatic real estate photos for sales brochures, and more, according to news reports. There's just one hitch: Those businesses were likely flouting the law, because the Federal Aviation Agency (FAA) had all but banned commercial drone use until late last year. But in 2015, businesses will have the chance to apply for exemptions from this prohibition, comment on FAA's proposed rules for small drones (or sUAS), and start to develop their drone strategies.

Camera-equipped drones are now available at hobby stores for as little as $300. Drones are typically cheaper and more nimble than manned aircraft; sophisticated sensors allow them to "see" and "hear"; and hard drives and Internet connectivity allow them to store massive amounts of data. They could someday become indispensable for agriculture, mining, real estate, security, research, deliveries, and more—as is already the case in many countries such as Canada, Japan, and Australia. The Association for Unmanned Vehicle Systems International (AUVSI), a trade group, estimates that drones could become an $82 billion, 100,000-job industry segment within 10 years of the FAA's allowing their integration into the National Airspace System. "One day soon, it will not be at all unusual to drive past a farm and see drones flying over it," says Gerry Murphy, co-chair of Crowell & Moring's Aviation Group.

But a runaway drone could pose a hazard to a person or a plane, so the FAA is taking a very cautious approach. Through the FAA Modernization and Reform Act of 2012 (FMRA), Congress ordered the FAA to publish final regulations for sUAS (under 55 pounds) by August of last year, and to integrate drones into the National Airspace System by September 2015. But the agency is behind schedule. As of last fall, it had yet to issue even a proposed rule for sUAS. Once the FAA does, citizens and businesses will have an opportunity to comment. The sUAS rule could be finalized as early as the end of 2015, Murphy predicts, though it will more likely take until mid-2016.

Some small businesses have begun using drones despite the FAA's ban, claiming that the FAA lacks the necessary authority (or the manpower) to police the skies. But as of late last year, about 150 businesses had taken a more prudent approach: they've applied for regulatory exemptions pursuant to Section 333 of the FMRA. Last fall, the FAA approved the first exemptions for commercial use in the mainland U.S., for seven aerial film production companies that now have the right to use small drones for "scripted, closed-set filming for the motion picture and television industry." The FAA agreed with the companies' contention that small drones were safer than conventional aerial filming using a manned aircraft. And late last year, the

FAA granted five additional Section 333 exemptions for use of sUAS in aerial surveying, oil rig flare stack inspection, and other applications that are seen as "dull, dirty, and dangerous."

But the exemptions are still considered by some to be too restrictive. The drone must fly slower than 50 knots, must fly below 400 feet, and must remain within line-of-sight of a pilot who must have at least a private pilot's certificate and use a separate observer. Operators must also submit flight plans and follow detailed maintenance procedures. While the initial rounds of Section 333 exemptions were encouraging, they suggest that the FAA may be similarly restrictive when it proposes its general operating rules for sUAS. "The FAA is unlikely to retreat from strict pilot certification requirements or distinguish between different types of sUAS," Murphy says.

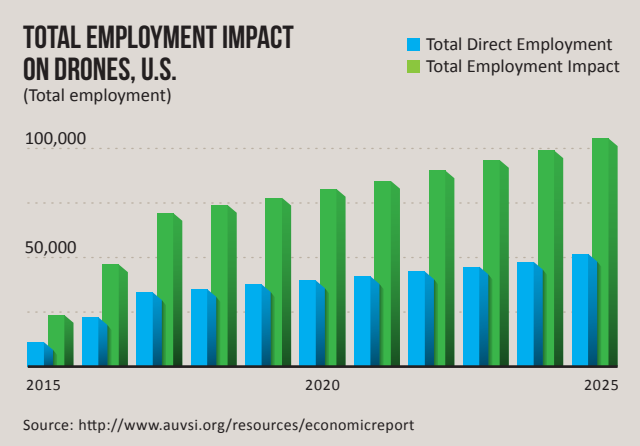
Observers who expect a flood of Section 333 exemptions in 2015 may be disappointed, Murphy adds. "The FAA has set a high bar for future exemptions, and the agency has only so much bandwidth to review exemption petitions."

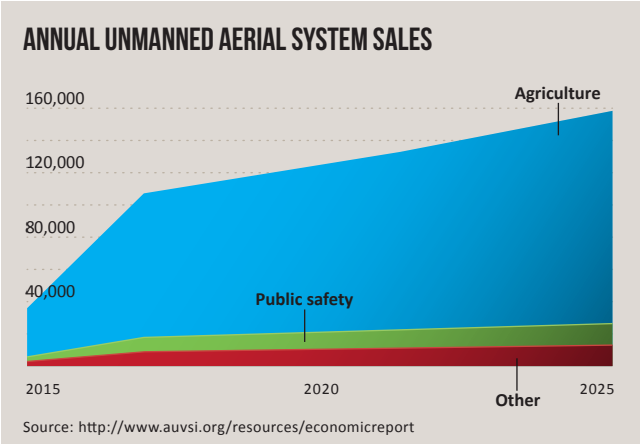
Beyond this, companies that wish to use drones face other hurdles. One is the public's concern about privacy, as drones could be used to harass or spy on individuals undetected. Several states have approved laws restricting drone use due to privacy concerns, while many others are contemplating similar legislation. Ultimately, companies using drones may have to cope with a patchwork of state-level privacy laws, Murphy says. Another concern is cybersecurity, as a "hacked" drone could be put to nefarious uses. Eventually, certain commercial drones may need to utilize dedicated radio spectrum frequencies, and anti-hacking technologies will mature, Murphy believes.

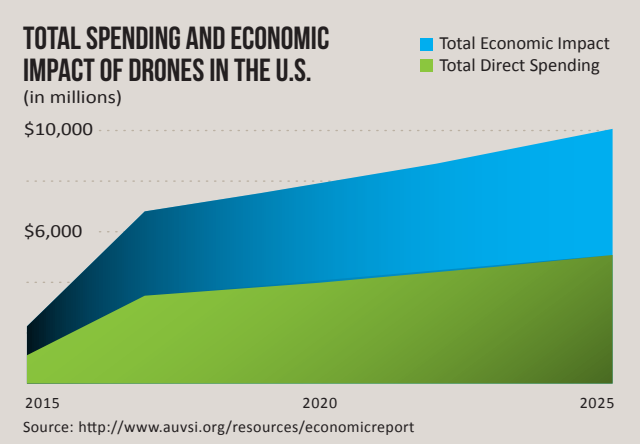
Given all the obstacles that drone operators could face, companies are likely to outsource their drone needs to dedicated service providers, Murphy predicts. Such operators would offer modular drone platforms that could be equipped with different sensor packages or photo/video capabilities depending on the mission at hand. And those operators would likely provide related services for the collection, analysis, retention, and storage of data. That said, some industries may adopt widespread drone use fairly quickly. "The most significant use, far and away, will be in precision agriculture," Murphy says. "Then you'll see drones used for facility inspections—chemical plants, oil and gas refineries, power lines, as well as for aerial surveying and natural resource prospecting."

Many of these uses will deploy small drones in areas that are sparsely populated and often privately owned, which will keep both safety and privacy concerns to a minimum. But other services—such as those planned for urban areas or utilizing larger drones—will have to wait a while longer before these concerns are resolved.

BUZZWORTHY







The trade group AUVSI estimates that business use of drones could have a major impact on the U.S. economy. These charts assume the FAA approves rules on commercial drone use.

DATA PRIVACY

MOVING TOWARD RISK MANAGEMENT

As more companies capture and use more data, and as more people and devices become more interconnected, regulators and consumers alike have grown increasingly concerned about data privacy and cybersecurity.

That's no surprise. It seems scarcely a week goes by without reports of another large company—and its millions of customers—falling victim to a data breach. Rather than waiting for and responding to a breach and headlines, companies recognize they can take many actions in advance of a cyber-incident.

"Companies are amassing customer data, they realize it's a tremendous asset, and they want to optimize their use of that asset," says Jeffrey L. Poston, co-chair of Crowell & Moring's Privacy & Cybersecurity Group and a partner in the firm's Litigation & Trial Group. "The flip side is that if that data is compromised, it can become a serious liability."

There will be efforts by various industries to self-regulate around data protection, Poston says. That won't prevent regulators from scrutinizing the issue. While the prospects for federal legislation, post-midterms, are uncertain, both federal and state agencies will likely become more aggressive in enforcement.

At the state level, there's significant variation in regulatory oversight. States like California enforce robust data-privacy regulations, "and California revises its regulations nearly every year," says Robin B. Campbell, co-chair of Crowell & Moring's Privacy & Cybersecurity Group. In June 2014, Florida passed the Florida

Robin Campbell, Evan Wolff, Cheryl Falvey, and Jeffrey Poston

Information Protection Act, expanding companies' obligations to protect personal information and establishing one of the nation's strictest breach-notification requirements.

At the federal level, "industry-specific federal agencies will become more aggressive in enforcement," Poston predicts. For example, he notes, "Health and Human Services' enforcement arm, the Office for Civil Rights, has signaled a willingness to go after even the smallest breaches and the smallest players."

Yet there remains no single federal legislation that covers data privacy generally. Into that void has stepped the Federal Trade Commission (FTC), offering broad advice for businesses and consumers alike, and increasingly strict enforcement of data privacy and cybersecurity. The sweeping enforcement authority of the FTC has held up in court. In April 2014, a federal judge ignored a defendant's argument that the FTC lacked broad power to regulate cybersecurity practices and to bring enforcement actions when such practices are deemed "inadequate," and allowed the FTC to proceed with its lawsuit alleging the company failed to adequately secure consumer information.

"But when the FTC requires security measures be 'adequate,' just what does 'adequate' mean?" Campbell asks. "There's no standard, and going forward there will be a lot of debate around this issue."

EMERGING FRAMEWORK

A standard is emerging, however, as the National Institute of Standards and Technology (NIST) released a "Framework for Improving Critical Infrastructure Cybersecurity." The Framework "provides a structure that organizations, regulators, and customers can use to create, guide, assess, or improve comprehensive cybersecurity programs," according to NIST.

"The Framework is intended to complement and work in coordination with a company's existing cybersecurity activities," says Evan D. Wolff, co-chair of Crowell & Moring's Privacy & Cybersecurity Group. "It can be a useful tool to get companies to focus on preparing for an incident, investing in real compliance activities. And it can serve as a sound approach for companies to develop policies, governance, and technology controls based on an external standard that may be acceptable to federal and state agencies."

The Framework grew out of a February 2013 executive order (EO), "Improving Critical Infrastructure Cybersecurity." One directive of the EO was that government agencies should determine whether they have the authority to implement the Framework. "Agencies are now in the process of incorporating the Framework into current regulations," Wolff says.

ALWAYS ON

As regulation catches up to reality, technology surges ahead. The emerging Internet of Things—Internet-connected items ranging from home appliances to health care devices to car monitors—adds new wrinkles to data privacy.

More products incorporate tracking chips and sensors, and companies face tough decisions on the use of this technology to compete. Consumers may not be aware that the products they buy could expose their identity or location. For example, the interconnected home can sense whether you are awake or sleeping and even whether you are at home or not. Retail stores can leverage shoppers' smartphones to make real-time offers as they browse items. "At the heart of the emerging regulatory debate is how much security must be built into these interconnected products to withstand scrutiny post-breach," says Cheryl A. Falvey, co-chair of Crowell & Moring's Advertising & Product Risk Management Group.

The FTC has already taken enforcement action in a case against TRENDnet, a maker of wireless technology, over video monitors vulnerable to hacking. Under the FTC's consent decree, TRENDnet must designate employees accountable for security practices, audit risks in hardware and software design, engage service providers to maintain device security, retain relevant records for five years, and have its security activities assessed by independent professionals.

RISK TO REWARD

Data privacy will become top of mind for regulators and consumers as companies amass and leverage more Big Data. "More clients are coming to us saying, 'We have this new capability to gather and analyze customer data, and we want to understand how this affects compliance,'" Campbell says.

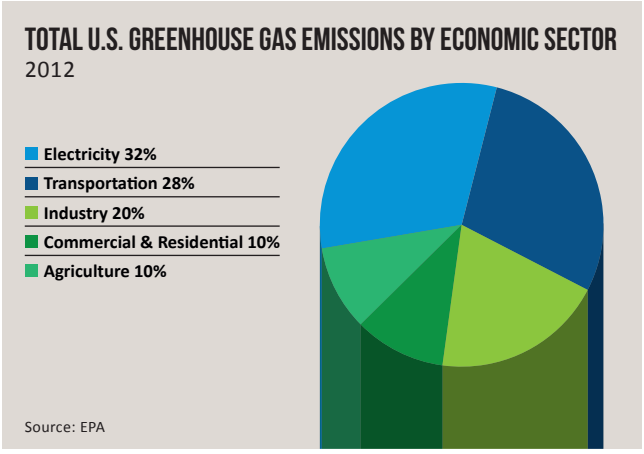
One important step is to view cybersecurity holistically and from the perspective of risk management, Campbell advises. Identify your most sensitive and highest-risk data. Understand how you collect it, how you store and use it, how it moves around in your organization, and whether partners or vendors have access to it. Document how you protect it, how you remediate and communicate potential breaches, and how you review and update policies and procedures.

"Concerns around data privacy are changing the way regulators look at compliance," Campbell says. "Regulators want to see companies conducting a comprehensive risk analysis."

ENVIRONMENT

UNPRECEDENTED

"It's not hyperbole to say the EPA's proposed greenhouse gas rules for the power sector would be far and away the most expansive regulatory rulemaking in U.S. history," says Chet M. Thompson, co-chair of Crowell & Moring's Environment & Natural Resources Group and former deputy general counsel at the Environmental Protection Agency (EPA).



The EPA has targeted emissions in the transportation and energy sectors. Industry and agriculture could be next.

In response to growing concerns around climate change, the EPA is placing intense focus on the reduction of greenhouse gases (GHGs), primarily carbon dioxide and methane. And in the absence of new legislation from a gridlocked Congress, the EPA is left to use existing Clean Air Act authority and programs, even though by all accounts they aren't designed to tackle this global issue.

The agency has proposed three major rules, all focused on fossil fuel-fired electric generating units:

2013 Proposed Carbon Pollution Standard for New Power Plants After receiving 2.5 million public comments on its 2012 proposal, the EPA proposed a new set of standards for newly built natural gas- and coal-fired power plants. Emissions standards for coal-fired units are based on carbon dioxide reductions achievable through use of carbon capture and sequestration technology, "a requirement that makes it very unlikely that a new coal plant will be constructed in this country anytime soon," Thompson says. The EPA expects to promulgate the rule in 2015, "and it will be challenged the day the rule is published in the *Federal Register*," he anticipates.

Clean Power Plan In June 2014, the EPA proposed new rules to reduce carbon emissions from existing power plants. The rules will set emissions standards or "guidelines" that each state must achieve by 2030. The EPA is also developing state-specific standards based on each state's unique mix of power generation and opportunities to shift load to lower-emitting generation sources such as wind and solar. The goal is to reduce carbon emissions from the power sector by 30 percent from 2005 levels. The comment period closed in December 2014, and the EPA has announced its plan to finalize the rules by June 2015. These rules will also be challenged by states, industry, and nongovernmental organizations—in fact, 11 states and one major coal producer have already filed suit without waiting for the rule to be finalized.

Proposed Carbon Pollution Standards for Modified and Reconstructed Power Plants Also in June 2014, the EPA issued proposed emissions standards for "reconstructed" and "modified" power plants. Reconstructed plants are those in which the capital cost of new components exceeds half the cost to build a new facility. Modified units are those to which physical or operational changes result in increased emissions. The EPA's proposed rules will likely disincentivize plants from making upgrades, even if doing so improves efficiency, says Thompson.

"What the EPA is doing with these proposals is unprec-

Chet Thompson and David Chung

edented and will have wide-ranging impacts for the country," Thompson explains. "In the past, the EPA essentially regulated at the individual unit level, promulgating emission standards based on reductions that could be achieved by units with well-controlled emissions. Now, the agency is proposing standards based on reductions achievable through regulation of the electricity grid as a whole. This has the effect of dictating to states the makeup of their energy sector. Many observers believe the EPA's proposed system-based approach exceeds its authority under the Clean Air Act."

WATER NEXT TIME

The EPA's GHG rules most directly affect the power sector. But organizations like the U.S. Chamber of Commerce, the National Association of Manufacturers, and other industry groups have also taken notice.

In part that's because energy costs and infrastructure affect virtually every sector. But it's also because many believe the power sector is only the first of many in the the EPA's crosshairs. "The petroleum industry in general will be next," Thompson says. "Hydraulic fracturing for shale gas and shale oil is already under consideration. The cement industry, which generates a lot of carbon dioxide, is likely. Agriculture should also be watching this."

But the EPA won't stop with air-quality standards. The agency will also focus on water, Thompson believes. In March 2014, EPA proposed a rule that would broaden the federal government's authority over additional waters of the United States.

The Clean Water Act gives the EPA authority over "waters of the United States," Thompson explains. "How broad the EPA's authority is depends on how that phrase is defined," adds David Chung, counsel in Crowell & Moring's Environment and Natural Resources Group. "Bays, navigable rivers, the Great Lakes are all obviously waters. But what about ephemeral drainages, industrial ponds, and roadside ditches?"

The potential implications are significant. "For example, any time a company or landowner wants to undertake activities in or near a ditch or low spot that happens to be wet after it rains, there could be costly and time-consuming permitting requirements and exposure to enforcement litigation," Chung notes.

In the meantime, there remains regulatory uncertainty. Finalization of the new rules for power plants will likely occur after the June 2015 target date, but it will almost certainly happen this year. Numerous legal challenges have already been lodged, and the court battles will only escalate. "This will end up in the Supreme Court, where the EPA will have an uphill battle," Thompson predicts.

The Supreme Court has upheld the EPA's authority to regulate GHGs. But the Court has also made clear that the agency's authority has limits. "The power to execute the laws does not include the power to revise clear statutory terms," Justice Antonin Scalia wrote in *Utility Air Regulatory Group v. Environmental Protection Agency*. "[The Court is] not willing to stand on the dock and wave goodbye as EPA embarks on this multiyear voyage of discovery," he continued.

Still, the Obama administration has clearly decided that one of its signature efforts will be the regulation of GHGs. "There's a small window for this administration to get these things done," Thompson says. "So we'll see some aggressive regulatory activity. There's no doubt this issue will dominate the legal landscape in 2015."

CONSUMER PRODUCTS AND ADVERTISING

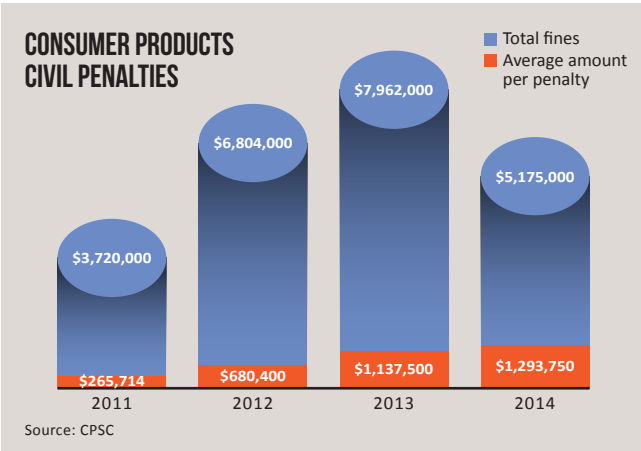
RECALL AS REGULATION

Agencies that govern consumer products aren't expected to engage in significant new rulemaking over the next year. But their increasing enforcement activities, especially around recalls, could have effects that are similar to new regulations.

In the United States, the Consumer Product Safety Commission (CPSC) and the Federal Trade Commission (FTC) have sharpened their focus on compliance. Key areas of emphasis include ingredients in food and other consumer products, the emerging Internet of Things category, and consumer advertising.

"What's different is that both the CPSC and the FTC are looking not only at the matter at hand but also at how the company will behave going forward," explains Cheryl A. Falvey, co-chair of Crowell & Moring's Advertising & Product Risk Management Group and former general counsel of the CPSC. In a typical settlement, a company might agree not to sell a particular product that has been deemed unsafe. "Now we're seeing more expansive language that requires the company to have a program that monitors incident reports," she says, "or to have a testing program through which it can verify claims."

This is happening especially through product recalls. Instead of formal rulemaking, or in place of developing standards for a product category, the CPSC is pushing for voluntary recalls. "When there are multiple recalls in a product category, it becomes a de facto rule that the product doesn't meet a standard or is banned from sale," says Laura Jastrem Walther, counsel in Crowell & Moring's Advertising & Product Risk Management Group and Product Liability & Torts Group.



While the number of civil penalties against consumer products companies decreased in 2014, the average fine per penalty continues to grow.

CONTENTS MAY SETTLE

Of growing interest to the CPSC, the FTC, and the public at large are product ingredients—in food, cleaning products, health and beauty products, and more. Regulators are especially concerned about chemical safety, "organic" or "all-natural" claims, and the presence of genetically modified organisms, or GMO, ingredients. "These are regulatory areas that increasingly spill over into class actions," Walther warns. "Consumers believe that they're paying a premium for all-natural products, so they have high expectations."

There will also be scrutiny around all things related to children—whether or not the product in question is targeted at them. An example is the magnetic desk toy Buckyballs, which the CPSC essentially forced off the market, claiming they posed a hazard to children. In October 2014, the Commission issued a final rule setting strict standards for magnet sets, "but initially the CPSC didn't propose a new rule or say there should be warning labels," Walther says. "Instead, it forced recalls and essentially banned the product by those means." The rulemaking came only later.

Natalia Medley, Laura Walther, and Christopher Cole

Safety concerns are extending to the Internet of Things—Internet-connected devices such as home appliances, security systems, and the like. This could be of growing interest to both the CPSC and the FTC. "If an Internet-connected device is hacked, that could obviously be a privacy issue," Walther says. "But if the breach causes a product like a smoke detector to fail, then it's a safety issue as well."

FROM PRIVACY TO DISCLAIMERS

The FTC has been increasingly consumed with data privacy, says Christopher Cole, co-chair of Crowell & Moring's Advertising & Product Risk Management Group. For example, the Commission has brought cases against online merchants over children's ability to make purchases in applications (so-called "in-app purchases") without their parents' consent.

In 2014, Apple agreed to pay at least $32.5 million and Google at least $19 million to settle FTC complaints that the companies billed consumers for millions of dollars of charges incurred by children through mobile apps.

Going forward, the FTC will focus more on the adequacy of disclosures in advertising. The agency is looking especially at online and mobile ads.

"In magazine and TV ads, there might be a disclaimer displayed at the bottom of the page or screen," Cole explains. "On a smartphone screen, the FTC is saying, that disclaimer could be too difficult to read."

PRODUCT SAFETY IN THE EU

While the United States grapples with enforcement, the European Union (EU) is watching two major pending regulatory measures. The EU is close to substantially revising its product-safety regime with the Consumer Product Safety Regulation (CPSR) and Market Surveillance Regulation (MSR). Both address product identification and traceability, require risk analysis and management, and increase market surveillance by member state authorities.

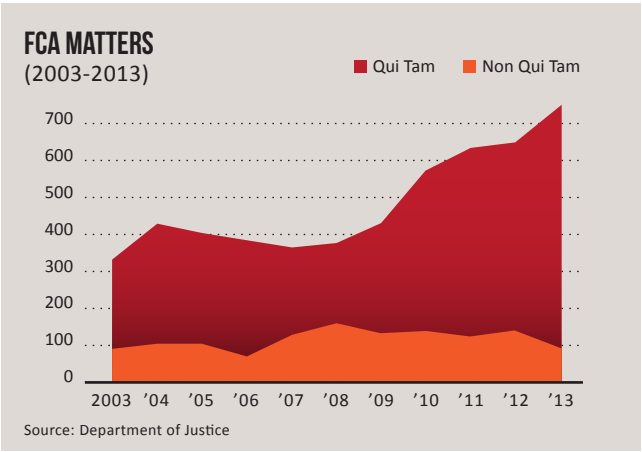
The regulations have been passed by the European Parliament and are being considered by the Council of Ministers, with finalization expected by the spring of 2015. "Businesses should understand what these regulations could mean for products distributed in the EU and how they may affect global compliance strategies, particularly when compared with what's required in the U.S. and other countries," explains Natalia R. Medley, counsel in Crowell & Moring's Washington, D.C., office and a member of the firm's Advertising & Product Risk Management Group and Product Liability & Torts Group.

Whether in the U.S. or Europe, companies should ensure their compliance program is robust and responsive. "The best defense is to perceive issues early," Cole says. For example, he advises monitoring social media to see what people are saying about products and advertising. If product issues emerge, report them promptly. "Product issues are sometimes unavoidable," Cole concludes. "Don't compound them with late reporting."

GOVERNMENT CONTRACTS

IT COMES BACK TO COMPLIANCE

Government contractors will continue to face uncertainty in the year ahead—from restoring budget cuts to levels of overseas military activity, from executive orders to expanded liability under the False Claims Act (FCA).



Qui tam actions have increased markedly over the past few years.

The good news is that sequestration hasn't had as dire an impact on government contractors as some observers predicted. In part that's because of the repeal of previous automatic spending cuts and Congress's setting higher caps on discretionary and mandatory spending in 2014 and 2015. The question is how long this will remain the case. "That's an especially open question for contractors that support the military," says Angela B. Styles, co-chair of Crowell & Moring's Government Contracts Group and former administrator for Federal Procurement Policy at the Office of Management and Budget (OMB). "When the military isn't fully engaged, it eventually trickles down to contractors." The military drawdown in Afghanistan will continue, though a residual force will remain.

Emerging threats around the world—from the Islamic State in Iraq and Syria (ISIS) to the outbreak of diseases like Ebola—will continue to require military responses, resources, and additional funding, says David C. Hammond, a partner in Crowell & Moring's Government Contracts Group who advises contractors deploying personnel overseas in support of U.S. missions.

"Military dollars flowing to contractors will remain flat or decrease in the next year," Hammond says, "but the impact will continue to vary contractor by contractor." For contractors that support expanded airborne operations in Southwest Asia, deployment of Special Forces, training of foreign forces fighting ISIS, or intelligence gathering, a decrease in spending is unlikely. Contractors supporting cyber or border security can expect more activity over the next two years. In other areas, "acquisition timelines will be stretched or funding reduced, leaving potential gaps in a company's pipeline," he adds.

DRIVING AN AGENDA

Regardless of the amount of procurement funding in 2015, executive orders (EOs) will continue to have an impact on contractors. The Obama administration is using EOs to drive its broader policy agenda. "Government contractors are often on the front lines of implementing policy," Hammond points out. For example, while President Obama unsuccessfully pushed Congress to raise the minimum wage for all workers, in January 2014, he signed an EO to establish a minimum wage for government contractors.

That wasn't the only EO advancing the president's labor agenda. In July 2014, the administration issued the Fair Pay and Safe Workplaces Executive Order, targeting contractor compliance with federal labor laws. The order aims to create several new obligations for federal contractors and subcontractors around paycheck transparency, dispute resolution, and self-disclosure of violations of labor laws. Going forward, "we'll

David Hammond and Angela Styles

see more proposed regulations on enforcement of labor laws and consequences for violations," Hammond believes.

There may also be spillover from the administration's environmental policy. "We may see more executive orders intended to impose consequences on contractors for violations of environmental laws as well as requirements for certain 'green' initiatives," Hammond predicts.

DEBARMENTS, QUI TAM ACTIONS

Government contractors will also see the number of suspensions and debarments increase, and types of conduct triggering suspensions and debarments will likely expand. "Congress has been sending the message through hearings and legislation that agencies aren't taking a tough enough stance," Styles observes.

Agencies have received the message. This includes an increased focus on a prime contractor's oversight of its subcontractors' compliance efforts. This reflects a continuing trend emphasizing outsourcing compliance throughout the supply chain and increased scrutiny of mandatory disclosure requirements. "Simply flowing down clauses, which has been the traditional mode of operation, is no longer sufficient," Styles says. Subcontractor oversight should include periodic audits, program reviews, and requirements that subcontractors demonstrate they have sufficient policies, systems, and procedures in place. "Link the growing emphasis on suspensions with the Federal Acquisition Regulation's mandatory disclosure rule, and more people will report issues and we'll see more suspensions," she adds.

Also increasing will be FCA, or "*qui tam,*" actions filed by whistleblowers, which could have significant implications for contractors. A case in point is *Kellogg Brown & Root Services Inc. v. United States ex rel. Carter,* in which the U.S. Court of Appeals for the Fourth Circuit significantly expanded how the FCA can be used against contractors. First, it increased liability under the Wartime Suspension of Limitations Act. It did this by allowing private plaintiffs to bring civil *qui tam* actions without any time restriction when the government is engaged in "armed hostilities"—a term the Fourth Circuit found to include military engagements without a formal declaration of war. Second, it decided that the "first-to-file" provision of the FCA allows duplicative *qui tam* actions as long as the earlier action is no longer pending.

If the ruling is upheld by the Supreme Court, "potential liability would not be limited by any statute of limitations, because we no longer start wars with congressional declarations, nor do we end them on a declared date," Hammond says. Defending against alleged conduct that occurred well past the FCA's six-year statute of limitations—or in certain circumstances, up to 10 years—would often impose prejudice and undue burdens on the contractor being sued. Memories fade, personnel move, and documents are lost over time.

At the state level, contractors can expect to see an increase in the number of false claims actions filed under state law as states seek new revenue streams to address tight budgets.

Looking ahead, even with the new Republican majority in Congress, the ongoing political stalemate will likely mean no significant new budget deal before the 2016 elections. But depending on those election results, some new rules may be rescinded, just as George W. Bush rescinded certain EOs by Bill Clinton that targeted government contractors.

Regardless of which party is in office, the focus among government contractors should be on compliance. "It always comes back to compliance," Hammond says. "Every dollar you invest in compliance will likely avoid $10 in costs to rectify a material noncompliance."

"For many government contractors, losing a contract can be a virtual death sentence," Styles concludes. "So treat government customers like the precious commodities they are."

INTELLECTUAL PROPERTY

PLAYING OFFENSE AND DEFENSE

As businesses enter developing markets, they should work to shape the IP landscape.

In an innovation age, little is more precious to a business than its intellectual property. And business executives are keenly aware of the importance of protecting that property in every major market where they do business. In many developing countries, governments are increasingly coming to grips with the importance of IP protection to expanding domestic industry and attracting foreign investment. For Western enterprises expanding overseas, it is therefore an important time to help shape the IP protection landscape in their key emerging markets. There is no better place to do this than in the trade arena—in individual countries, through bilateral and plurilateral trade agreement negotiations, and through multilateral organizations such as WIPO.

Many developing countries are nearing an inflection point for their IP systems, says Teresa Rea, a partner in Crowell & Moring's Intellectual Property Group, a director of C&M International, an international policy and regulatory affairs consulting firm affiliated with Crowell & Moring, and a former

Kate Clemans, Teresa Rea, and Patricia Wu

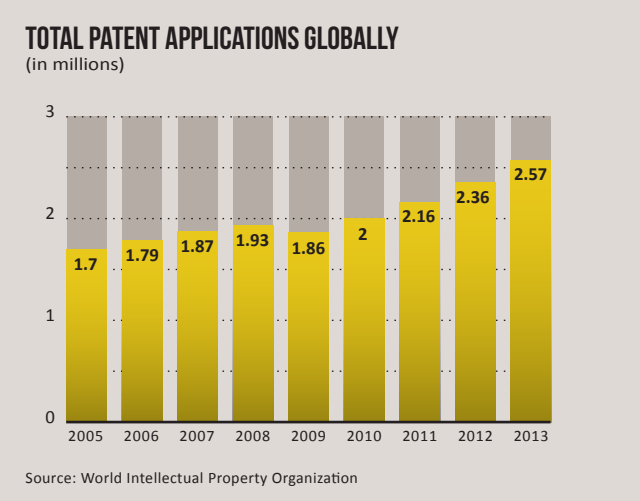
acting and deputy director of the U.S. Patent and Trademark Office. "Many of them have a history of weak IP protection and policies of requesting low-cost technology transfer from trading partners. But now they'd like to transition into knowledge-based economies. Every country today is focused on innovation, and IP is the engine for that innovation. All of these countries want to create the next Amazon or Apple, and they have a lot of smart people. But they don't have strong legal systems to enforce IP rights."

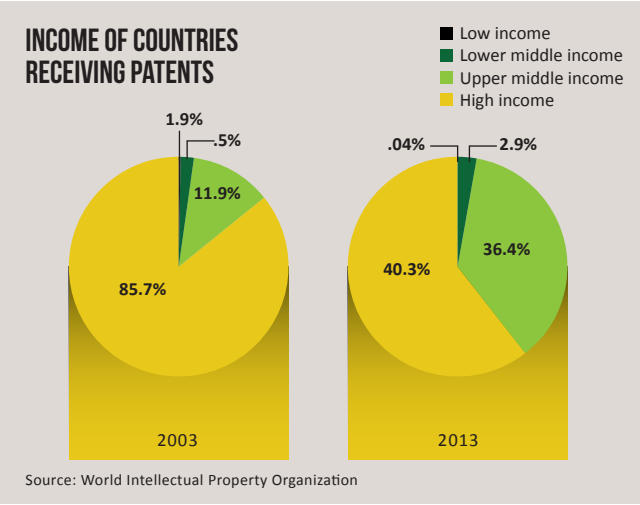
Developing countries can be spotty in their application of IP protections to right holders, but that is changing. The story is becoming more complex in some countries, notes Patricia Wu, a director of C&M International. One example is biodiversity-rich countries like Brazil, which are keen to monetize genetic resources found in areas like the Amazon—resources that after much research and development can ultimately end up in pharmaceuticals, cosmetics, and other products. But increasingly Brazil is also a user of intellectual property. "As any economy develops and becomes more mature, the number of stakeholders grows and their interests change," Wu says. "This provides an opening to shape IP policy in those countries."

In China, for example, officials are working to modernize the IP system, notes Rea. China's most recent Five-Year Plan contains metrics such as the number of patent applications and new commercial products. But major problems remain, and the system needs to operate more efficiently with effective deterrents.

Entering and growing in these markets therefore requires having an IP strategy that is both offensive and defensive. "The right conversations prior to entering overseas markets can have an impact on everything from advertising to expansion. And there's much existing enterprises can do by using IP to improve their position," notes Rea. "Companies should also consider leveraging government-to-government channels and regional discussions among governments," adds Kate Clemans, a senior director of C&M International. "These often can provide context for a company's conversation with the government, and in a constructive setting."

Improving IP protection in a country includes enforcement of IP rights, the application of enforcement in the courts, and transparency. Transparency is key when it comes to the rulemaking procedures that lead to regulations that protect innovation, says Clemans. "More countries now see value in opening up the regulatory process as we do [in the U.S.] by incorporating a consultative mechanism with industry and other stakeholders." Open consultation helps to avoid unintended consequences of regulation, which can be costly to both the stakeholder and the government.





Global patent applications have risen by two-thirds since 2005, and by about 250 percent since 1995 (top). While most patent applications are still filed in high-income countries, a growing slice is being filed in low income through upper middle income countries (bottom).

Partnerships are also demonstrating to countries how to value their own IP, according to Clemans. For example, the APEC Biomedical Technology Commercialization Training Center, launched in Seoul this past December, was founded by members of the Asia-Pacific Economic Cooperation forum with the goal of facilitating transfer of research discoveries into cost-effective therapies, in part by helping innovators understand how to value their discovery, protect their IP, gain access to financing, and enter into appropriate licensing arrangements. It is this sort of shared capacity building that will provide real results and allow countries to become knowledge-based economies.

"IP protection should be a win-win for everyone," Rea says. "It should go hand-in-hand with marketing your products. Whether you're opening your own country's market or increasing market access overseas, it will make your products available to more people."

TRADE CONTROLS AND TREATIES

BIG FINES, NEW DEALS, AND "SMART" SANCTIONS

Free trade is on the rise—but businesses must be careful to avoid enforcement risks when seizing opportunities.

As globalization pushes forward, the potential rewards—from trade, from expansion, from partnerships—have multiplied. But then again, so have the risks.

Federal authorities have taken aggressive action on companies, both domestic and foreign, accused of breaching sanctions, laws, and regulations. In 2014, for example, a major bank was fined a whopping $9 billion for allegedly doing business with Sudan and Iran. The bank was fined for transactions that generally occurred in France and the Europe Union (EU) and were legal under French and EU law, notes Cari Stinebower, a partner in Crowell & Moring's International Trade Group.

The enforcement trends that Stinebower sees in sanctions, export controls, anti-money laundering, and anti-corruption are similar to those Crowell & Moring attorneys are seeing throughout the rest of regulated industry: growing coordination by federal agencies, growing civil penalties, and settlements that impose monitors and in-depth audits of risk-based compliance programs.

Stinebower, who helped implement the USA PATRIOT Act when she was an attorney-advisor at the Treasury Department, says the Act empowered more aggressive action by federal authorities against companies that might be supporting malicious activity. U.S. companies with overseas operations and

Cari Stinebower and John Brew

dealings—and also non-U.S. firms with U.S. operations or dealings—must all remain vigilant about U.S. laws.

Cooperation is growing among enforcers in different countries as well, also aimed at combating mutual foes. Hence the growing use of "smart sanctions." More precise than sanctions that target entire countries, smart sanctions target individuals, individual organizations, or even specific kinds of transactions that supposedly aid an antagonist such as Iran, Syria, and, more recently, Russia.

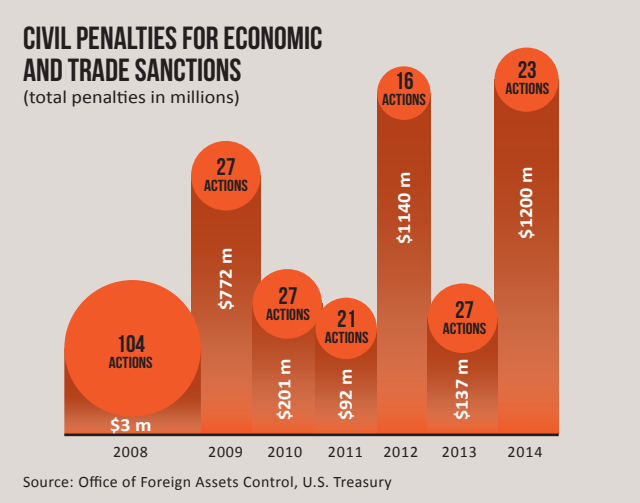
Smart sanctions are an alternative to military action or broader sanctions that hurt innocent people. But for companies that are deputized as the frontline for enforcement, they can be a real headache, Stinebower says. Now, compliance staff must do more than forbid transactions with certain parties. As a result of the more nuanced prohibitions, compliance officers often must monitor individual transactions with sanctioned entities, which may require being embedded within a business unit.

Compliance officers are also grappling with conflicts between data privacy laws and sanctions requirements, Stinebower adds. "On the one hand, a multinational entity is expected to centralize compliance to maintain a high standard and is held responsible for the work of foreign subsidiaries and affiliates," she says. "But on the other, the data cannot lawfully be sent across jurisdictions—or worse, in some cases, even screened against the U.S. lists of prohibited parties."

Meanwhile, compliance officers at companies with any U.S. touch point are also expected to implement controls to ensure that the components and raw materials in their products are neither sourced from, nor sent to, sanctioned parties or jurisdictions. Depending on the sanctioned party, these controls can be very rigorous. "For example, let's say a U.S. company buys and imports a $40,000 piece of manufacturing equipment from a Chinese company," Stinebower says. "Unbeknownst to the buyer, the seller sourced 10 cents' worth of gold from North Korea for use in a part. That's a sanctions violation for the buyer."

PROMOTING TRADE

On a more cheerful note, 2015 has the potential to be a major year for proponents of free trade. Negotiations are still underway for both the Trans-Pacific Partnership Agreement (between the U.S. and 11 Pacific Rim countries, not including China) and the Transatlantic Trade in Partnership Agreement (between the U.S. and the EU). Both agreements promise to do much to streamline, harmonize, or eliminate trade rules and increase market access on both sides. Every industry stands to be affected, including automobiles, financial services, pharmaceuticals, and chemicals, says John Brew, a partner in Crowell & Moring's International Trade Group.



Civil penalties levied by the U.S. Treasury are reaching new heights.

The agreements have received support from both major parties in the U.S., but their passage ultimately depends on politics. In the past, major trade agreements have only passed when the president has received Trade Promotion Authority, a special privilege granted by Congress that allows agreements to be passed by an up-or-down vote. Because Republicans tend to favor open trade, and now that Republicans have control of both houses, Brew believes that the new Congress may move forward with granting Obama this authority—meaning there is an increased chance the agreements will be passed, with the Trans-Pacific Partnership leading the way.

Meanwhile, customs agencies worldwide are tightening rules and stepping up enforcement. In some cases, this threatens to undo trade negotiators' efforts to reduce trade barriers, Brew says: "For example, many countries are making it more difficult for companies to obtain duty-free treatment or claim other trade preferences that resulted from free-trade agreements."

As with other areas of enforcement, agencies within the U.S. are increasingly cooperating and coordinating their enforcement of trade rules through efforts such as the new Border Interagency Executive Council. What's more, customs agencies worldwide are also coordinating their efforts. For example, increasingly, multiple countries in a region will take a trade action against a given U.S. company, Brew says. They are using existing and new regulations to try to get companies to increase the declared value of their products, thereby increasing the duties they must pay. And there has been an increase in anti-dumping and countervailing duty proceedings in the U.S. and elsewhere. All these trends seem likely to continue through 2015, Brew says.

Customs duties are a major source of revenue for countries. The question is, are countries willing to push so hard for these revenues that they undermine their leaders' declared support for free trade?

ANTITRUST

CHINA, IP, AND BIG DATA RISING

With a global economic environment spurring consolidation, it's no surprise there has been greater transactional scrutiny by regulators. But the volume of M&A deals won't be the only factor affecting antitrust enforcement over the next 12 months.

Shawn Johnson and Ryan Tisch

Three trends will continue to reshape the contours of the antitrust landscape. First is heightened scrutiny of mergers involving U.S.-based firms by agencies worldwide but particularly in large emerging economies like China. Second is a heightened focus on the application of the antitrust laws to intellectual property. And third is the intersection of antitrust law with Big Data.

The number of deals in 2014, while high, wasn't as large as many predicted based on the stockpiles of cash U.S. companies are sitting on, points out Shawn R. Johnson, a partner in Crowell & Moring's Antitrust Group. But as the global economy builds steam in 2015, M&A activity will rise. "That will include deals of all sorts, including more strategic transactions in pursuit of scale economies that raise real competitive concerns," Johnson says.

Those concerns won't just come from the Federal Trade Commission (FTC) and Department of Justice (DOJ), or even the European Commission (EC). From Brazil to Ecuador, from India to Taiwan to Ukraine, about 100 jurisdictions now have a merger-notification regime. And many of those nations are increasingly aggressive in their antitrust review.

That places a new onus on U.S. companies. While the FTC and the DOJ take it upon themselves to assess transactions, many countries base their approach on precedent set by the EC. In these jurisdictions, parties must provide their own analysis of potential competitive effects of a proposed merger—increasing their administrative burden.

What's more, merging companies need to apply for clearance not just in their countries of origin, notes Ryan C. Tisch, also a partner in Crowell & Moring's Antitrust Group. "Increasingly, companies need approval wherever the merged entity will do business, and even in some places the merged entity won't do business," he says.

Antitrust agencies around the world have also become more aggressive in attempting to align their respective regulatory reviews. "That was certainly the case during United Technologies's acquisition of Goodrich" in 2012, Johnson recalls. "In large, multinational transactions, the agencies are actively attempting to avoid situations in which one agency closes its review while other investigations are ongoing." All of that requires greater planning and greater coordination among outside and in-house counsel. And despite counsel's best efforts, this trend can still result in additional delay.

MIDDLE KINGDOM MERGERS

A key antitrust change agent will be China. "China's Anti-Monopoly Law has been in effect for just over six years, and

until just a few years ago, China didn't have an active scheme to review foreign mergers," Tisch says. "Today the China Ministry of Commerce, or MOFCOM, is actively investigating not just mergers but also potential price fixing and monopolies."

What's more, the Chinese law is focused particularly on mergers involving foreign parties. That issue garnered international attention in 2009 when China blocked Coca-Cola's bid to acquire Huiyuan, a Chinese juice purveyor. "The beverage market in China is hugely fragmented, so there was the perception that there should be no competition issues," Tisch explains.

Since then the pace has increased. In June 2014, MOFCOM sank the merger of three shipping giants, Denmark's AP Møller-Mærsk, France's CMA CGM, and Switzerland's Mediterranean Shipping Co. The deal had already won U.S. and European approval.

In July 2014, Chinese regulators raided the offices of Microsoft and its partner Accenture as part of an anti-monopoly investigation of the software company. In September they turned their attention to Chrysler and Volkswagen, fining the carmakers a total of $46 million for allegedly conspiring with dealers to maintain high prices.

"U.S. companies need to know how to work with MOFCOM, because it expects to be treated with the same deference as the FTC and the DOJ as it rapidly grows in sophistication and resources," Tisch says. Filings with MOFCOM nearly tripled from 72 in 2009 to more than 200 in 2013. "And that number will be higher going forward," Tisch believes.

SHADES OF IP

Mergers won't be the only focus in 2015. In the U.S., regulators are digging even more deeply into competitive issues associated with intellectual property. The intention is to determine whether IP is different from other kinds of economic property and therefore should be treated differently under antitrust law.

In August 2014, the FTC received approval from the White House Office of Management and Budget for an economic study of the business models and tactics of so-called patent-assertion entities (PAEs). PAEs use patents primarily for threatening and filing lawsuits rather than making products.

Johnson doesn't expect a dramatic shift in the position of the FTC or DOJ on this issue. "But we will likely see increased scrutiny of the acquisition of patent portfolios and the IP aspects of other transactions," he says. Tisch agrees. "Manufacturers and technology companies with large patent estates will need to manage these issues carefully to preserve the value of their patents," he says.

Another area to watch is "fair, reasonable, and nondiscriminatory"—or FRAND—licensing terms for "standard-essential patents." These are patents that are so integral to a technology standard that companies can't make products that conform with the standard without the patent. "The FTC has been active here, and it will continue to be," Johnson predicts.

EU: FURTHER COMPLEXITY

The same trends will drive developments in the European Union in 2015. But complexity is added by the replacement, as the EU's head of competition, of the arch dealmaker Joaquin Almunia by Dane Margrethe Vestager. Brussels-based Crowell & Moring partner Sean-Paul Brankin, a former legal director at the UK Office of Fair Trading, says, "Ms. Vestager has some big issues on her plate: the Google case, which Mr. Almunia did not settle, and the proposed extension of EU merger control to non-controlling minority shareholdings. Mr. Almunia was known for engineering remedies, even on hotly debated matters. Early indications are that Ms. Vestager will take a more cautious approach, at least initially. The market is watching to see what comes after."

Sean-Paul Brankin

BIG DATA, BIG MONOPOLY?

As more companies in more industries embrace Big Data, the collection and use of customer information will also come under increasing scrutiny. The FTC has so far taken the most interest in data issues, given its dual role enforcing both antitrust and consumer protection laws. But both the FTC and DOJ will ultimately take interest in the antitrust implications of Big Data.

For example, a company that freely shares its data with partners to allow them to reach customers and then withholds that data could run afoul of some modern permutation of the "essential facilities" doctrine. Companies' practices in the gathering and sale of data could also put them at risk under classic antitrust theories about exclusive dealing or even cartel behavior. Likewise, regulators might look at the antitrust implications of massive data stores that result from a merger, Tisch anticipates. "Data has emerged as a new asset class," Tisch says. "This is a new and uncharted territory for everyone."

WHITE COLLAR

MAKING UP FOR LOST TIME

White-collar prosecutors are more aggressive—and intrusive—than ever. But they're also willing to negotiate.

In the wake of the 2008 financial crisis, regulators and prosecutors alike were criticized for letting financial institutions and other supposedly culpable companies off the hook. Now, it seems, they are making up for lost time. Huge fines, intrusive "creative" settlements, and aggressive enforcement against executives are trends that seem likely to continue through 2015.

In recent years, several major banks have faced eye-popping penalties. But the levies were only the beginning, as many companies are also being required to change policies, appoint monitors, and more. "Beyond the fines and civil penalties, companies are agreeing to settlements that address the corporate structure and corporate culture in an attempt to change how these companies are run going forward," says Glen McGorty, a litigator in Crowell & Moring's White Collar & Regulatory Enforcement Group.

Companies are agreeing to the terms as an alternative to a

Tom Hanusik, Glen McGorty, and Shamiso Maswoswe

criminal indictment or conviction, which can destroy business and brands before legal challenges are resolved. The specter of a 2002 Arthur Andersen and a 2005 Riggs National Bank is still very present around negotiating tables and boardrooms. Thanks to precedents like these, where criminal charges left the companies collapsed or acquired, it's very rare for a public company to even risk a trial on a white-collar case, McGorty says.

Federal agencies are also being more aggressive in civil and criminal prosecutions of individuals in white-collar cases. High-profile cases include the dozens of insider-trading convictions won by the Manhattan U.S. attorney and the upswing in individual prosecutions under the Foreign Corrupt Practices Act, or FCPA. One indication of prosecutors' expanding reach: the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) are prosecuting foreign-born executives working for foreign-based companies.

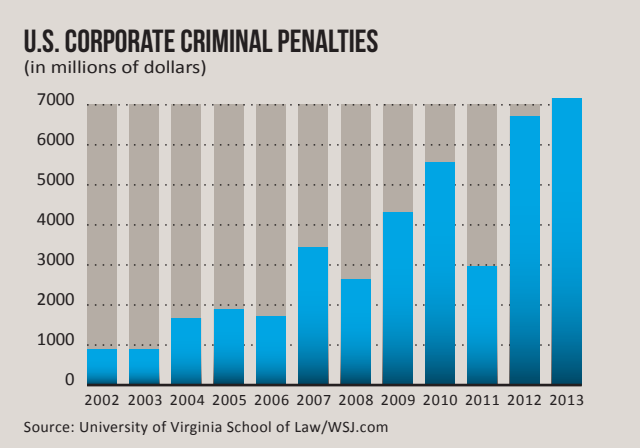
"U.S. prosecutors they can target executives because their companies are listed on a U.S. stock exchange, even if those executives never even visited the U.S.," says Shamiso Maswoswe, counsel in the White Collar & Regulatory Enforcement Group. "They appear to be willing to bear the cost and challenges involved in extradition, obtaining foreign evidence and the extraterritorial application of U.S. law in the hope of deterring future misdeeds by foreign nationals. Whether or not that is an effective allocation of limited resources remains to be seen."

Other indications of agencies' toughening stance on white-collar crime, according to McGorty:

- The DOJ and the SEC have been working together more closely on parallel civil and criminal proceedings.
- SEC Chair Mary Jo White has said that her agency will go after ever-smaller "broken window" cases in order to prevent problems from growing.
- The DOJ and the SEC are more willing to pursue even very complicated accounting fraud cases. When they can't find direct evidence of accounting fraud, prosecutors are pursuing non-fraud violations, such as failing to keep accurate books and records.

THE HIDDEN UPSIDE

A feature in *The Economist* last August lambasted this enforcement surge. "The problem is not just that companies are ever more frequently treated as criminals," *The Economist* said. "It is that the crimes they are accused of are often obscure and the reasoning behind their punishments opaque, and that it is far from obvious that justice is being done and the public interest is being served."



In the years since Enron's collapse, prosecutors have been seeking larger fines from companies.

Indeed, prosecutors are claiming unprecedented powers, and compliance costs are growing. But there's an unexpected bright side, at least for companies that can skillfully navigate the new environment. As compared to a criminal indictment or conviction—for which the consequences can be both calamitous and wholly unpredictable—a settlement provides considerable room for negotiation well beyond the size of the penalty.

Based on their experience as monitors and as counsel to monitors, McGorty and Tom Hanusik, chair of the White Collar & Regulatory Enforcement Group, say there are several other elements to settlement that can be negotiated:

- Will the agreement be a "non-prosecution agreement," where no criminal charges are filed and the company self-monitors for a relatively short period of time? Or will it be a "deferred prosecution agreement," when charges are filed and suspended pending successful completion of probation?
- Will a corporate monitor be appointed? And if so, by the court, by the company, or negotiated between the company and the prosecutors?
- How long will the probationary period last?
- What kind of powers and mandate will the monitor have?

Even the prosecutors' public announcements are often highly negotiated, Hanusik says. If a news release on a settlement with a public company is vague on what crimes were alleged to occur, it may be at the company's request. "The more that's disclosed, the more risk the company faces of derivative actions, shareholder class actions, or other civil lawsuits," Hanusik adds.

And even the probationary period, as intrusive as it may be, has a purpose. "By the time you get to a resolution, companies want to get it right," Hanusik says. "Investigations are incredibly disruptive and fines are expensive. Executives will do what it takes to avoid another one so that they can get back to running their business."

INDUSTRY FOCUS: HEALTH CARE

A NEW WORLD ORDER

Health care has been the hottest news on the regulatory front for the past two years. But the industry should brace itself for continuing change in 2015.

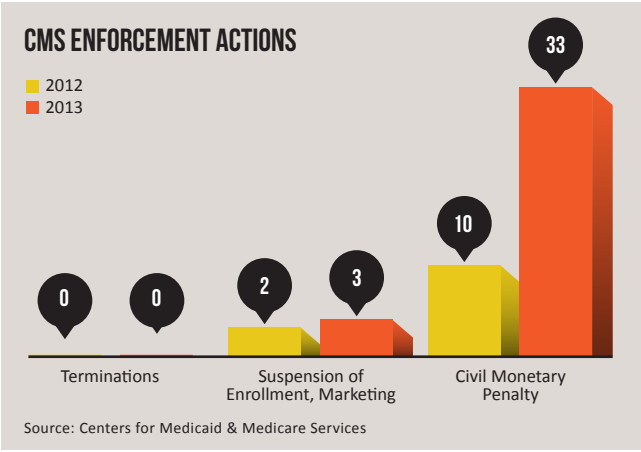
Why? Because that's when many implications of the Affordable Care Act (ACA) will come to fruition. The results will include dramatic expansion of administrative burdens, standards, and regulatory auditing and enforcement for insurers, providers, and other industry players.

One key reason for the increase in administrative burden is the auditing the Centers for Medicare & Medicaid Services (CMS) will be doing to ensure compliance with newly implemented ACA programs. For example, CMS has begun audits to ensure compliance with the Medical Loss Ratio (MLR) program implemented in 2012. The MLR rule requires health insurance companies to spend a certain percentage of premium dollars on medical services—80 percent in the individual and small-group markets and 85 percent in the large-group market. Issuers are required to issue rebates to enrollees if they fail to meet the minimum standards.

Other areas that will be targets of CMS auditing include the risk-sharing programs—reinsurance, risk adjustment, and risk corridors, often called the "3 Rs." These programs are designed to ensure premium and market stability, particularly in the early years of the ACA.

The transitional reinsurance program is a $25 billion program, in place from 2014 to 2016, that provides funding to plans that insure higher-cost enrollees in the individual market. The risk-adjustment program pays or charges insurers in the individual and small-group markets based on whether an insurer's actuarial risk for the year is greater or less than the average. The risk corridors program, applicable to qualified health plans (QHPs) offered in the individual and small-group markets, limits losses and gains beyond an acceptable range.

"CMS has been busy putting these programs and rules in place," explains Teresa Miller, a partner in Crowell & Moring's Health Care Group and former acting director of the Oversight Group at CMS's Center for Consumer Information and Insurance Oversight (CCIIO). "In 2015, we'll see an increase in monitoring compliance with the MLR program and the 3 Rs programs. That will mean no small administrative burden for insurers."



Civil monetary penalties by CMS increased markedly between 2012 and 2013.

RAISING STANDARDS

QHPs must be certified by a marketplace before they can be sold. CMS slightly raised QHP certification standards for the federally facilitated exchange for 2015 plans, "and we'll see more changes going forward," Miller predicts. For 2014 plans, CMS largely deferred to states to review for compliance with QHP certification standards such as network adequacy. But during the 2015 certification process, CMS also reviewed plans'

Troy Barsky, Teresa Miller, and Christine Clements

compliance with network adequacy standards.

That's a concern for insurers, "because anytime CMS and the states look at the same issue, there's the possibility they'll come to different conclusions," resulting in regulatory confusion, Miller says. For example, while the National Association of Insurance Commissioners already has a model law that governs network adequacy, CMS has indicated it may develop its own standard.

CMS will also likely increase the scrutiny of plans for discriminatory benefit design. "A primary focus will almost certainly be drug formularies," Miller notes. Consumer groups filed a complaint against insurers in Florida for allegedly discriminating against HIV/AIDS patients by placing drugs that treat HIV/AIDS in high cost-sharing tiers within their formularies. Complaints of this kind are putting pressure on CMS and the states to do more to ensure compliance in this area.

HEALTH CHECK

New standards will likely drive government audits and enforcement, which have been increasing in size and scope. "The ACA gave the government more tools to combat fraud, waste, and abuse, especially in the Medicare and Medicaid programs," says Troy A. Barsky, a partner in Crowell & Moring's Health Care Group. Such enforcement will affect not only insurers but also providers, like hospitals, clinics, and physicians.

The government is focused on rooting out fraud and abuse before it occurs, rather than paying and chasing federal dollars after the fact. "CMS wants to become more like credit-card companies that detect fraud as it is happening," Barsky says.

One example of this government effort focuses on home health agencies that provide health care services in the home. Historically there has been a high level of fraud prosecution against these providers. "In regions such as South Florida, Detroit, Dallas, Houston, and Chicago, the government has used new legal authorities to prevent new entities from enrolling in the program, to stop providers from defrauding Medicare or Medicaid," Barsky notes.

One major driver of enforcement will be Big Data—the vast amounts of health information government agencies capture. Big Data will be increasingly influential in at least two ways, Barsky says. First, government will leverage health information such as referral and claims data to track patterns and detect potential fraud, waste, and abuse in near real time.

Second, government will increasingly release health data to the public. For example, CMS recently released Medicare physician payment data. "That revealed many details about high utilizers and potential new areas of government focus," Barsky notes. Likewise, the ACA mandates the release of information about payments by drug and medical-device makers to physicians and academic medical centers. States are now passing their own "sunshine" provisions. "For 2015, insurers and providers will need to question what data may be released," Barsky says, "and whether the release of that data will impact business practices and decision making."

Finally, the ACA's focus on efficiency and accountable care will drive further industry consolidation and other transactions. That will lead to increased government scrutiny and regulation, says Christine M. Clements, another partner in Crowell & Moring's Health Care Group. With fewer health care dollars available because of sequestration and other payment reductions, coupled with government payments tied to quality and efficiency, payers and providers are looking for ways to maximize revenue and keep that revenue "in the family." As a result, "Insurers are buying providers, and providers are starting their own health insurance plans. There's a blurring of traditional lines, and the current regulatory scheme will have to play catch-up," Clements says.

In the meantime, the federal government is turning up the heat on health plans. "CMS took more enforcement actions against Medicare plans in 2013," Clements observes. "The federal government is holding health plans accountable for not only their own performance but also that of their subcontractors. We'll see these trends continue in 2015."

INDUSTRY FOCUS: ENERGY

WHO FLIPS THE SWITCH?

As energy continues to top the regulatory issues affecting a broad range of companies, conflicts are emerging between federal and state energy regulators.

Larry Eisenstat and Patricia Alexander

"In many cases there's no clear policy as to what's the province of the federal government and what's the province of the states," says Larry F. Eisenstat, chair of Crowell & Moring's Energy Group. "That will mean uncertainty for companies operating in these markets. It will also mean litigation."

Both the conflicts and attendant uncertainties have primarily arisen from the need for a rapid and large-scale build-out of gas-fired and renewable generation, as well as the infrastructure required to support such a build-out. They will be exacerbated by the retirement of an aging generation fleet, by the Environmental Protection Agency's (EPA) proposed Clean Power Plan developed under Section 111(d) of the Clean Air Act, and by the U.S. shale-gas boom, which has made natural gas abundant and affordable.

The industry also is on the cusp of significant changes affecting electric markets, driven by the increasing importance of demand response and energy efficiency, storage, distributed generation, regional transmission expansion, resource adequacy, and reliability requirements.

"Federal and state governments each have their own regulatory spheres, but what one does affects the other," observes Patricia Alexander, a senior policy advisor for Crowell & Moring who spent two decades at the Federal Energy Regulatory Commission (FERC). "They will have to learn to work together, and, as they do, it will mean a year of change, perhaps dramatic change, for companies in the energy industry."

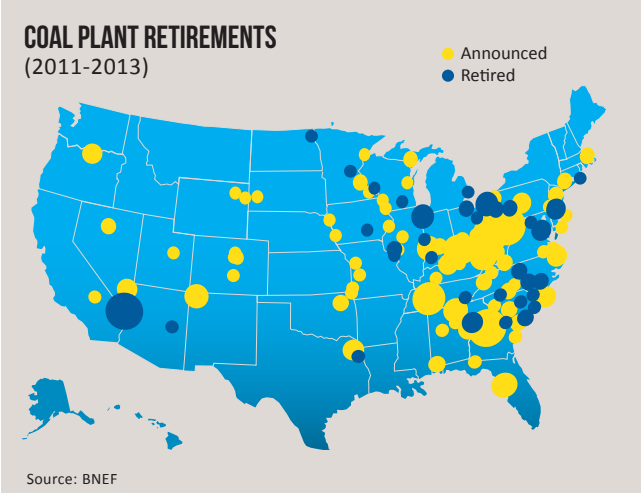
PLANNING FOR CLEANER POWER

The EPA's proposed rules for regulating greenhouse-gas emissions from existing power plants will be finalized in 2015. Those rules will be challenged in the courts.

"Fifteen to 20 states have already sued the EPA," says Dave Freudenthal, former governor of Wyoming and senior counsel for Crowell & Moring. "We'll also see litigation from various industries and industry groups. At first that litigation will focus on Washington. But as each state implements its own plan under EPA guidance, litigation will turn to each state in which companies do business."

Overall, though, the new EPA rules are likely to survive. "I think this will go to the Supreme Court and be upheld, because for the most part the Court seems to back the EPA in its interpretation of the Clean Air Act," Eisenstat says.

The regulation will drive the replacement of coal-fired power plants with natural gas and renewable sources, as well as the build-out of infrastructure such as natural gas pipelines and electric transmission lines. That will require coordination among the EPA, FERC, the North American Electricity Reli-



Nearly 14 gigawatts (GW) of coal generation was retired between 2011 and 2013, and another 32.5 GW of retirements was announced.

ability Corp., regional transmission organizations, public utility commissions, and state environmental regulators. These organizations do not necessarily have a track record of cooperation.

CALL AND RESPONSE

One key issue will be demand response—incentivizing customers to reduce their electricity usage during peak demand. FERC had required regional markets to compensate demand-response providers at the same rate as the generator selling power. "In other words, if the market price for electricity is $100, any consumer reducing its energy use by that amount would be paid $100," Alexander explains.

When that notion was challenged, the court found that only states, and not FERC, could set pricing for demand response. "This creates a jurisdictional quagmire for markets that span multiple states," Alexander says. "How will state decisions about demand response be integrated into FERC's regional markets?"

That's not the only issue where FERC and states are at cross-purposes. In regions where natural gas infrastructure requires significant investment, such as the Northeast, revenues available under FERC-regulated tariffs aren't sufficient to induce generators to commit to the firm delivery services needed to fund new pipelines.

POWER POTPOURRI

Numerous other regulatory issues will emerge over the next year, Alexander predicts. On distributed generation, the line between federal and state regulation is unclear. Even where it's governed by states, distributed generation will affect FERC's regulation of grid reliability.

On the construction of new electricity transmission, utilities are implementing FERC's new regional-planning and cost-allocation rules established, in part, to reduce litigation with the states over pricing rules that allocate costs over many states. In that same rule, FERC ordered that federal tariffs no longer could include rules preventing competition for the right to construct transmission projects. However, the states continue to be able to prevent such competition when exercising their authority to site and approve the construction of those projects.

Finally, states have grown dissatisfied with the failure of FERC's markets to incentivize new generation sited in-state or nearby. States are trying to establish programs to provide out-of-market revenues to ensure construction of the resources they prefer. And even though the states, and not FERC, have exclusive authority over generation, states have run into challenges.

"For example, Maryland and New Jersey awarded long-term contracts to new gas-fired generators," Eisenstat says. "But the contracts were attacked and judicially invalidated on the grounds that the states unlawfully sought to preempt FERC's authority to regulate in organized markets." Some believe those decisions are so broad that any state-mandated renewable-energy program in a FERC-organized market could be challenged.

FERC AND MARKET MANIPULATION

The Federal Energy Regulatory Commission (FERC) has become increasingly aggressive in its enforcement efforts. One area of focus is electricity market manipulation—the attempt to interfere with competitive market outcomes.

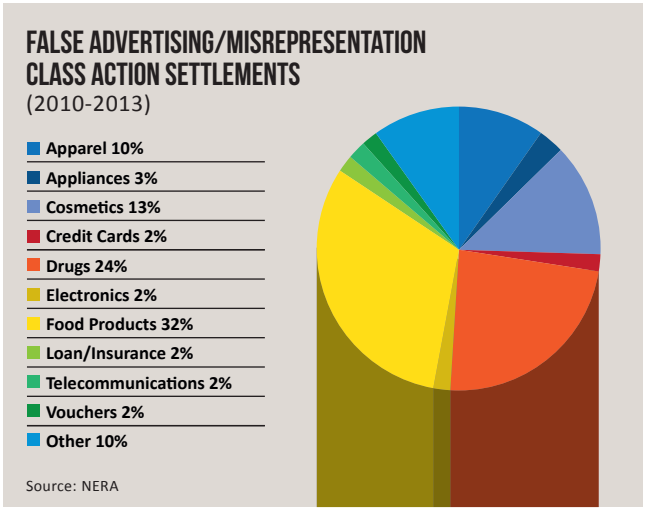
In 2013, a major financial institution agreed to pay more than $400 million to settle FERC allegations that it manipulated power markets in the Midwest and California. The same month the agency assessed a similar penalty to another major bank, also for market manipulation involving its trades in Western markets. In 2014, the bank won a court order putting the fine on hold while the company challenges the lawsuit.

"Some in the industry are concerned that FERC is defining market manipulation incorrectly," says Patricia Alexander, a senior policy advisor for Crowell & Moring.

"FERC believes that a particular activity doesn't need to be expressly prohibited in a tariff to be considered illegal," says Larry F. Eisenstat, chair of Crowell & Moring's Energy Group. "As cases wind through litigation, we'll see whether the courts will support FERC's views or force it to pull back." In the meantime, he advises, if a company is uncertain about the legality of an activity, "ask your general counsel or, if possible, ask FERC itself."

INDUSTRY FOCUS: FOOD

IS IT NOW REGULATION À LA LITIGATION?



Nearly one-third of false advertising class-action settlements between 2010 and 2013 involved food industry products. Note: Percentages total more than 100% due to rounding.

A broad regulatory structure exists for food products, addressing what they contain, how they're labeled, and how they're marketed. Still, the next 12 months will likely see a growing volume of class-action litigation around precisely those issues.

There are two reasons for this. First, "consumers are looking for more organic products, more 'all-natural' products, more products free of genetically modified organisms," says Steven D. Allison, a partner in Crowell & Moring's Litigation Group. "So more food makers are making claims in this regard—and being challenged in the courts."

Second, as opportunities for lawsuits involving targets such as asbestos and tobacco wane, a sophisticated, well-funded plaintiffs' class-action bar is seeking new targets. "Many issues around food ingredients and claims haven't been resolved yet in the courts," says Jennifer S. Romano, also a Crowell & Moring Litigation Group partner. "Food products are the next area where plaintiffs' counsel can try to develop new law."

At left, Jennifer Romano and Steve Allison. At right, John Fuson.

Such activities could extend beyond the courtroom. California Proposition 37 was an unsuccessful 2012 ballot initiative that would have required labeling of foods containing GMOs. But there will be more such efforts—such as ballot initiatives in Colorado and Oregon—as advocacy groups and the plaintiffs' class-action bar "press statutory and regulatory measures that are helpful to their causes," Allison predicts.

In the meantime, class actions will function much like new regulations. "Class actions can be incredibly expensive for food makers," Romano notes. "In many cases, companies are forced to change their behaviors simply to avoid a challenge by a class-action suit, just as they would in response to new regulations." Likewise, in a growing number of court settlements, companies agree not only to pay claims but also to change behavior—for example, establishing testing programs to verify claims.

TO SERVE AND PROTECT?

Class actions won't be the only issue affecting the food industry in 2015. The Food and Drug Administration (FDA) has been crafting new regulations to implement the 2011 Food Safety Modernization Act (FSMA). Several rules are expected to become final in the next 12 months.

In particular, final rules requiring food makers to establish food-safety and food-defense plans are likely, says John Fuson, a partner in Crowell & Moring's Advertising & Product Risk Management Group and former associate chief counsel at the FDA. A food-safety plan describes controls in the manufacturing process to prevent hazards such as contamination and spoilage. A food-defense plan, in contrast, is intended to prevent the intentional adulteration of food—for example, through sabotage or terrorism.

The FSMA also gives FDA new authority to detain food the agency believes is adulterated. In the past, the agency had to obtain court orders to prevent distribution of contaminated food. Now, FDA can detain food on its own for a limited period of time. What's more, "if you don't have an adequate food-safety plan," Fuson says, "any food you make will be considered adulterated and subject to detention."

INDUSTRY FOCUS: HIGHER EDUCATION

REGULATORY CHANGES SET THE STAGE FOR LITIGATION

Kris Meade, Peter Eyre, and Laurel Malson

In areas such as cybersecurity, labor and employment, and sexual misconduct, school officials are increasingly under the microscope. For higher education officials charged with protecting both students and taxpayer dollars, the list of challenges seems likely to grow in 2015.

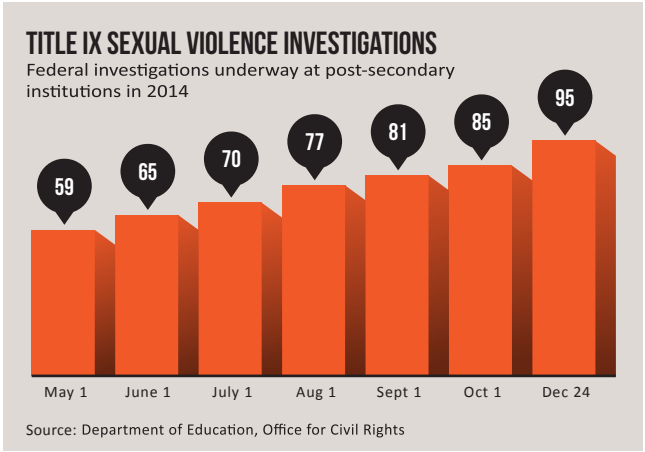
Last year, schools faced an onslaught of cyberattacks from sources both foreign and domestic. Colleges and universities are tempting hacking targets because they harbor a wealth of sensitive data including health and financial records and valuable intellectual property, notes Laurel Pyke Malson, co-chair of Crowell & Moring's Education Practice. "At the same time, they face cultural barriers to implementing safeguards restricting access to data, because their defining mission is to expand access to knowledge."

Many schools work with even more sensitive information—from the Pentagon, for example—because their faculty and students conduct research under federal contracts and grants. "These schools now face a slew of additional rules obligating them to report cyber incidents to the federal government and to take stronger measures to protect their entire data infrastructure," says Peter Eyre, a partner in Crowell & Moring's Government Contracts Group.

As federal government contractors, many schools are also grappling with a host of pending labor regulations as part of the Obama administration's pay equity initiative. Perhaps the most vexing would potentially require disclosure of aggregated compensation data by race and gender across a number of job categories. "The reporting requirements would be particularly onerous for colleges and universities because they don't classify their employees according to those job categories," notes Kris Meade, chair of the Labor & Employment Group at Crowell & Moring. "The results could spur audits targeting discriminatory pay disparities. But the data won't account for the many unique qualities of university compensation, such as how faculty compensation is often tied to winning research grants." (For more on the regulatory challenges facing contractors, see Government Contracts, page 26.)

But the highest-profile issue universities face today is their response to allegations of sexual misconduct. After several well-publicized incidents, the Department of Education revealed in late 2014 that it was investigating 92 schools for Title IX sexual harassment and assault violations. "Universities are grappling with multiple sub-regulatory guidance documents articulating some of the standards for responding to these violations," Malson says. "They're trying to reconcile new guidance with old guidance. A White House task force has released its own recommendations. And then there are the lawsuits. Many universities are in turmoil about how to best manage these compliance obligations."

Universities are being expected to conduct fact-finding investigations and manage quasi-judicial tribunals, all with an understanding of the nuances of sexual violence and trauma. "For the most part, they don't have the personnel to perform these functions," Malson says. With more guidance and debate likely to be forthcoming, she adds, "schools should continue reviewing their sexual misconduct response procedures, and respond diligently to any complaints that arise."



Investigations into campus sexual violence have risen steadily since the Department of Education began listing.them last May.

INDUSTRY FOCUS:
CHEMICAL REGULATION AND CYBERSECURITY

Federal authorities are revamping—and strengthening—laws on chemical products, site security, and cybersecurity.

The most significant chemical regulation reforms since the 1970s are poised to take shape in 2015, and they will impact just about every sector of the economy. Manufacturing, energy, transportation, retail, health care, and other industries will likely be faced with big changes and growing scrutiny pertaining to how their products impact health. At the same time, administrative actions are paving the way for new standards for cybersecurity, safety, and security at industrial facilities.

CHEMICAL REGULATION REFORM BILL

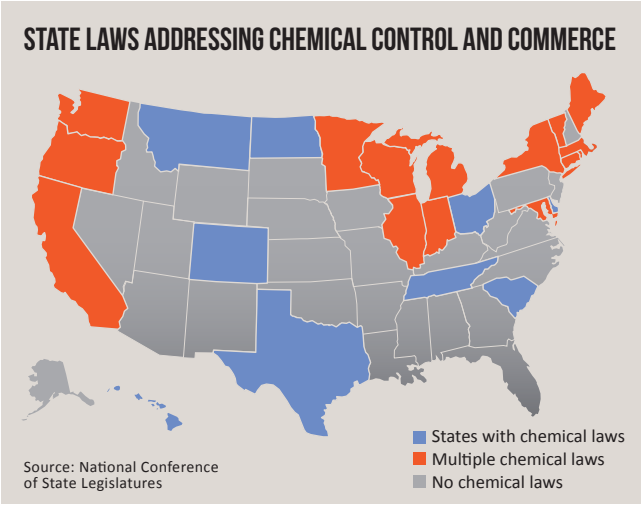
In 2015, changes in the law could mandate, for the first time, that the Environmental Protection Agency (EPA) conduct safety reviews of every chemical used in commerce. That's the central feature of legislation proposing the first serious reform of the Toxic Substances Control Act (TSCA) since its debut in 1976. The bipartisan legislation stalled last year but has a significant chance of being revived—and passed—this year, says Warren Lehrenbaum, a partner in Crowell & Moring's Environment & Natural Resources Group.

"If the legislation passes, EPA will be looking at chemical ingredients that companies have relied on for decades," Lehrenbaum says. "Some of these ingredients may be banned for certain uses, such as consumer uses. And ultimately, companies may have to reformulate their products or retool their industrial processes in order to comply."

Despite these dramatic consequences, TSCA reform has the support of the chemical industry. Over the years, environmental activists frustrated with a perceived lack of federal oversight have backed hundreds of state bills aimed at disclosing or banning chemicals. In the most sweeping effort, California is now forcing manufacturers and retailers to seek safer alternatives to chemical ingredients in widely used products. While only a handful of product types have been targeted thus far, the size of California's economy ensures that "the ripple effects from these regulations will be felt across the country, if not the world," Lehrenbaum says.

Companies facing a patchwork of state regulations hope that "TSCA reform would restore faith in the federal regulatory system and predictability to the regulatory landscape," Lehrenbaum explains. "And as a secondary benefit, it would also shore up public confidence in products in commerce."

Some Senate Democrats opposed the 2014 version of TSCA reform because of a provision specifying that it would generally preempt state law. Lehrenbaum is optimistic that disagreements over preemption will be hammered out in the new Congress. Meanwhile, in 2015, the EPA is likely to resume its Endocrine Disruptor Screening Program, which requires



Many states imposed their own laws rather than waiting for an update of the TSCA, creating a compliance challenge.

Warren Lehrenbaum and Evan Wolff

manufacturers to conduct tests on certain tranches of chemical substances. And it will continue working to harness market forces to target chemicals of concern, for example, by revamping its "Design for the Environment" logo, created to single out consumer products that the agency considers environmentally preferable, and implementing the new ChemView portal.

Companies that rely on chemicals—not just traditional chemical manufacturers—should consider making themselves heard in the legislative and rulemaking processes for TSCA reform, Lehrenbaum says. And they should keep a close eye on the ways chemicals are being targeted at the federal and state levels. For example, if chemicals important to their business are on the EPA's ChemView portal, they should make sure that the information on the site is complete and accurate.

CYBERSECURITY AND SITE SECURITY

A 2013 explosion at a Texas fertilizer plant prompted federal officials to redouble their efforts to modernize rules on safety and security at industrial facilities. An executive order in the wake of the explosion has improved interagency cooperation and spurred valuable consultations with the private sector, says Evan Wolff, co-chair of Crowell & Moring's Privacy & Cybersecurity Practice and a former advisor at the Department of Homeland Security.

As 2015 dawned, the Department of Homeland Security undertook a review of the Chemical Facility Anti-Terrorism Standards, which were first implemented in 2007. The Standards took an innovative, risk-based approach to establishing performance standards for security, but the inspection regime proved difficult to execute and organizations faced challenges in creating a compliant site security plan. Having testified during the rulemaking process, Wolff hopes the revised standards reduce duplication by other regulatory regimes and simplify the process for non-manufacturers to create and comply with their security plans.

This year should also see increased attention to cybersecurity. "Private industry is evaluating how to use the new Cybersecurity Framework to enhance the protection of their systems," Wolff says. Created by the National Institute of Standards and Technology in consultation with industry, the Framework describes standards and processes that industry can use to address cyber risks. It reinforces the links between business drivers and cybersecurity activities, and provides guidance on privacy and civil liberties considerations. Implementation of the Framework is voluntary—at least for now. "The Obama administration has ordered agencies to assess if they have the authority to incorporate the Framework into their existing regulations," Wolff says. "And they will do so, to the extent they can."

This year will also see the implementation of an executive order issued late last year encouraging companies to share information on cyber threats. "Hackers often use the same techniques on different players in the same sector, so sharing information—especially in real or 'machine' time—can help stop them," says Wolff. The administration is trying to reduce the legal and business risks that may arise from information-sharing between competitors or with the government, he adds.

Increasingly, success in fighting cybercrime requires cooperation throughout the enterprise, Wolff says. Lawyers, IT professionals, managers, and communications professionals must work together and communicate regularly with the board because, with the stakes involved, he adds, "cybersecurity is becoming a board function."

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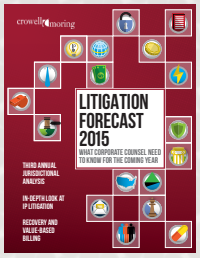

CROWELL & MORING'S THIRD ANNUAL *LITIGATION FORECAST*

As a companion piece to this year's new *Regulatory Forecast*, Crowell & Moring, since 2013, has produced *Litigation Forecast*. This year's volume includes a deeper dive into IP litigation—an area that is core to virtually all companies—as well as several business of law sections. To access an electronic version, go to www.crowell.com/LitigationForecast.