

# METROPOLITAN CORPORATE COUNSEL®

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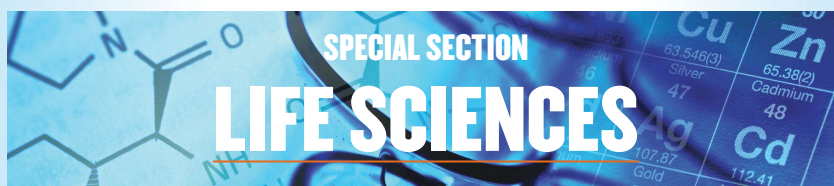
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PUBLISHER’S NOTE

Our goal in publishing *Metropolitan Corporate Counsel* and its various digital offshoots is to provide readers, most of them senior legal executives at major companies, with news and information that holds special appeal for them. That may be because it shines a light on legal and business issues facing their organizations, or because it helps them advance their careers, or because it holds up a mirror to the very special communities within which they work. We hope you’ll find some of all of that – and more – in this month’s issue.

First, we are adding more of your voices to *MCC*. That begins with Damien Atkins, general counsel of Panasonic Corporation of North America, who talks about his career and the culture of change he has been fostering in his first year with Panasonic, and Mark Nielsen, general counsel of Frontier Communications Corporation, who shares the playbook from its \$10.5 billion acquisition of Verizon’s operating subsidiaries in California, Texas and Florida. I encourage you to contact me if you’d like to join the conversation. You can be sure I’ll be contacting you.

Second, we are pleased to announce a new online publication, In-House Tech, which is designed to keep in-house legal executives and operations professionals abreast of cutting-edge risk, compliance and other issues related to technology and the management of sensitive data. Please have your IT professionals and legal operations leaders email [inhousetech@metrocorpcounsel.com](mailto:inhousetech@metrocorpcounsel.com) for their free subscriptions.

In this issue, don’t miss our special section on life sciences. Even if your company is not in the pharma or medical device businesses, there is plenty to learn from their intensive engagement with IP issues and strategies.

Our popular In-House Ops section offers an array of terrific contributions, including Lloyd M. Johnson’s “Tackling the Human Element of Transformation” and Altman Weil’s Rees Morrison on how analysis of a law department’s email activity can yield crucial information on both productivity and value.

In a signature *MCC* interview, Friso van der Oord, who heads strategy for the National Association of Corporate Directors, talks about an issue much on the minds of corporate board members: shareholder activism. Marks Paneth’s Erik J. Barr discusses the impact of proper valuations in pass-through entities, S corps and LLCs.

Finally, in the wake of the unsettling disclosures in the Panama Papers matter, we are delighted to feature Kelli Moll of Akin Gump on the evolving regulatory climate for hedge funds, and Hayden Isbister and Simon Dickson of Mourant Ozannes on the governance and litigation landscape in the Caymans and other offshore financial centers.

I continue to look for new opportunities to connect with readers and contributors. Please email me at [kcalve@metrocorpcounsel.com](mailto:kcalve@metrocorpcounsel.com) with your suggestions for new topics, publications or events we can host in your area.



Kristin Calve

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You can help us improve and expand services to corporate counsel by exploring with your company, your suppliers and law firms ways in which they too can join us as “Partners of Corporate Counsel.”

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# Briefly . . .

## News from contributors to *Metropolitan Corporate Counsel*



**Guy N. Halgren**

Sheppard Mullin's chairman of the executive committee, **Guy N. Halgren**, was re-elected to a sixth consecutive three-year term. Halgren was first elected to this management role in 2001. This is the first time a Sheppard Mullin chairman has held the position for more than three terms. "Our partnership is very fortunate to have Guy at the helm for another term. He's smart, fair, forward-thinking and focused on client service," said Lawrence M. Braun, a Los Angeles-based corporate partner and member of the executive committee. Halgren added, "I am honored to have been re-elected and [am] excited at the prospect of leading the firm to even greater heights, teaming with my vice chair, Jon Newby, and Managing Partner Robert Beall."

**David S. Reidy** has joined McGuireWoods as a partner in the San Francisco office. A financial services litigator with a practice advising financial technology companies, Reidy comes to McGuireWoods from Reed Smith, where he was a partner leading the FinTech practice. Reidy said, "I'm excited to be in on the ground floor of McGuireWoods' expansion into



**David S. Reidy**

the Bay Area. The firm is recognized nationally as a leader in financial services litigation, and I look forward to contributing to the firm's and our clients' continued success." Reidy received a bachelor's from Sonoma State University and a law degree from the University of California's Hastings College of the Law.

A firm-wide commitment to the United Way is evident in two recent elections of **McNees Wallace & Nurick** attorneys: **David M. Kleppinger** to a one-year term as chair of the United Way of the Capital Region board and **Katherine Pandelidis Granbois** to chair elect of the board of directors the United Way of Lancaster County. Kleppinger previously served as vice chair for the 2012 United Way campaign and chair for the 2013 United Way campaign.

Additionally, **James P. DeAngelo** of **McNees** has been appointed to a two-year term as president of the board of directors of the Pennsylvania Legal Aid Network. "Jim has been a part of this organization for a long time; his dedication and commitment to this organization, and to pro bono general-



**Katherine Pandelidis Granbois**

ly, is tireless," said colleague and friend Barbara Darkes.

**Jones Day** has announced two additions: **Eric Snyder**, a former assistant United States attorney (AUSA) for the Southern District of New York with significant experience in Latin America, has joined the Investigations and White Collar Defense practice, and **Michael Conway** has joined as a partner in the Financial Institutions Litigation and Regulation (FILR) practice. "With Eric, we're very fortunate to be the only law firm with a former AUSA on its white collar team in Brazil," said Ted Chung, leader of Jones Day's global Investigations and White Collar Defense practice. "Eric has successfully handled highly sensitive and complex matters of great importance to Brazil and other countries throughout Latin America. This has given him unparalleled insight into investigating and defending allegations of corruption and other misconduct, and in advising clients on compliance with the Foreign Corrupt Practices Act and other legal requirements." Jay Tambe, co-head Jones Day's FILR practice, said of Conway: "Mike has proved his mettle in dozens



**James P. DeAngelo**

of trials and arbitrations across the country, addressing numerous sophisticated financial disputes. He is a great addition to our multidisciplinary, global team, handling the intricacies of sophisticated financial products and guiding clients through the litigation and regulatory uncertainties they face with the myriad of ever-changing rules affecting financial institutions around the world."

Led by Patent Litigation group partners **Edward Reines** and **Adrian Percer**, both from the Silicon Valley office, **Weil, Gotshal & Manges** secured a major appellate victory for Adobe Systems on April 8, 2016. The federal circuit affirmed a California federal jury's verdict invalidating as obvious two digital-rights management patents asserted by plaintiff Digital Reg of Texas LLP. Additionally, Adobe will be reimbursed for attorneys' fees due to Digital Reg's litigation misconduct.

**Andrej Barbic**, co-chair of the Boston Patent Law Association's Contested Matters Committee, has joined the Boston office of **McCarter & English**, and **Gregory S. Shatan** has joined the New York office. "It's a win for the firm and, more important, a win for our clients when two attorneys like Andrej and Greg join us," said Michael P. Kelly, chairman of McCarter & English. "Our IP practice already is very successful and nationally renowned, and with their addition, we are now that much stronger. Andrej and Greg are both A-plus lawyers and A-plus people."

**Day Pitney** and Cohen Seglias Pallas Greenhall & Furman have launched a joint initiative investigating Title IX, which was enacted in 1972 to prohibit discrimination on the basis of sex in federally funded educational



**Eric Snyder**



**Michael Conway**



**Andrej Barbic**

*Continued on following page*



# Briefly...

News from contributors to *Metropolitan Corporate Counsel*

Continued from previous page



**Gregory S. Shatan**

programs and activities. “Our goal is to provide academic institutions with a team that has the necessary skills that are not generally found in educational facilities, including prosecutorial, investigative and Title IX litigation experience,” said Paul Thaler, Managing Partner of Cohen Seglias’ Washington, D.C., office. “In addition we understand the sensitivity required by academic institutions to oversee these investigations.”

**Jeffrey A. Wertkin**, a former trial attorney in the Commercial Litigation Branch of the Civil Division at the U.S. Department of Justice, has joined



**Jeffrey A. Wertkin**

**Akin Gump** as a partner in its litigation practice. “Jeff’s FCA trial and prosecution background, including his abundant work in the health industry, made him a very attractive candidate for us,” said Stephen M. Baldini, head of Akin Gump’s Litigation practice. “His extensive credentials, which include the relatively rare experience of trying a major false claims case to a successful jury verdict, will be an invaluable resource to our clients.” Wertkin received a J.D., as well as a Ph.D. in government, from Georgetown University and a B.A. from Haverford College.

**Weiguo “Will” Chen** has joined the Palo Alto office of **Sheppard Mullin**



**Betty Chen**

as a partner in the Intellectual Property practice group. “Will is a skilled IP practitioner and an excellent addition to our formidable IP practice group. He has a successful practice representing a variety of leading technology companies on patent prosecution, portfolio development, and patent and trade secret litigation,” said Guy N. Halgren, chairman of Sheppard Mullin. Chen joins the firm from Finnegan, Henderson, Farabow, Garrett & Dunner. He received a LL.M. from Franklin Pierce Law Center; a LL.B. and a B.S. from Tsinghua University in China; and a M.S. in electrical and computer engineering from Northeastern University.



**Matthew Evans**

**Fish & Richardson’s Betty Chen** has been selected for the Leadership Council on Legal Diversity’s 2016 Fellows program. A principal in the firm’s Silicon Valley and Austin offices, Chen previously clerked for Ron Clark of the Eastern District of Texas district court. She received a J.D. from the University of Texas Law School and a B.S. in business from the University of Southern California.

In addition, **Fish** has selected its own 2016 student Diversity Fellows. **Adam Aquino**, a student at the University of Chicago Law School, and **Juyoung “Jay” Kim**, a student at George Mason University School of Law, will work in the firm’s Washington, D.C., office. **Sarah Jack**, a student at the University of Iowa College of Law, will work in the Twin Cities office. **James Yang**, a student at Harvard Law School, will work in the Southern California office.

**Matthew Evans** has joined **AlixPartners** as a managing director of the firm’s Financial Advisory Services practice. “Matt brings to our clients a strong blend of financial and regulatory expertise,” said Simon Freakley, chief executive officer of AlixPartners. “His background and credibility strengthen AlixPartners’ financial investigative services offering and deepens our expertise in key areas of regulatory scrutiny. We are delighted to welcome him to the firm.” Evans received his bachelor’s degree in International Business from Ithaca College.

## PBI NAMES EVE RUNYON CEO

The board of directors of Pro Bono Institute (PBI) has named Eve Runyon its new president and CEO. Runyon succeeds Esther Lardent, who founded PBI and held the roles of president and CEO for 19 years. James W. Jones, chair of PBI’s board, said, “Eve is an excellent new leader for PBI who will build on the extraordinary foundation, vision, strategy and team that Esther Lardent so effectively put in place during her time at PBI. [Eve] has broad knowledge of the challenges and opportunities confronting the pro bono community and has clearly demonstrated her ability to lead PBI in the years ahead.”

Runyon joined PBI in 2005 as the director of corporate pro bono. Under her leadership, the department implemented many innovative initiatives to expand in-house law departments’ commitment to pro bono, including the Corporate Pro Bono Challenge, which enables law departments to identify, benchmark and communicate their support for pro bono service.

About her new position, Runyon remarked, “I am excited to have this opportunity to advance the legacy of Esther Lardent to promote and enhance access to justice through pro bono legal services. I am grateful for the commitment of PBI’s friends and supporters, and I look forward to working with our stakeholders to better serve communities in need.”



# The IRS' Position on HRAs

## *How the Affordable Care Act and HRAs interact*

By **Stephen R. Kern** / **McNees Wallace & Nurick LLC**

**T**he latest installment of guidance from the Internal Revenue Service (IRS) relating to employer-sponsored health plans was issued on December 16, 2015, in the form of IRS Notice 2015-87. The notice provides additional guidance and clarification on the application of the market reform requirements of the Affordable Care Act (ACA) to employer-sponsored health reimbursement accounts (HRAs). The notice represents the latest in a series of IRS pronouncements relating to the interaction between ACA and so-called "employer payment plans," which include HRAs.

Previously, the IRS stated that it considers any arrangement pursuant to which an employer reimburses employees for medical-related expenses to be a group health plan subject to ACA's market reforms. Unfortunately, these arrangements are unable to satisfy the ACA requirements (such as the prohibition on annual or lifetime limits) on a stand-alone basis and must, therefore, be "integrated" with an ACA-compliant group health plan (but not an individual market plan). This is true with respect to both pre-tax and after-tax reimbursement arrangements as well as to the direct or indirect reimbursement of any medical-related costs, including insurance premiums.

The notice provides new guidance and/or clarification regarding the following HRA issues:

### **Retiree Purchase of Individual Market Coverage**

In Q&A 1, the notice reaffirms previous IRS guidance providing that an HRA covering fewer than two participants who are current employees is not subject to ACA's market reforms. Accordingly, a retiree-only HRA may be used to purchase individual market coverage without causing the HRA to fail to comply with ACA's market reforms. This is true even if the amounts available to the HRA participants are determined in whole or in part by amounts credited during the period in which the individual participated in an integrated HRA covering active employees. It is important to note, however, that the retiree-only HRA will constitute an eligible employer-sponsored plan for any month during which the funds are retained by the HRA, thereby resulting in a participant in the HRA with available funds for any month not being eligible for a

premium tax credit with respect to the purchase of marketplace coverage for that month.

### **Employee Purchase of Individual Market Coverage**

The IRS reiterates its position that current employees may not use an HRA to purchase individual market coverage. Q&A 2 further clarifies this position by providing that even though amounts that were credited to an HRA covering an active employee while the HRA was integrated with another group health plan generally may be used to reimburse medical expenses in accordance with the terms of the HRA after the employee ceases to be covered by the other integrated group health plan, these credited amounts may not be used to purchase individual coverage after the employee ceases to be covered by the other integrated group health plan. In short, an HRA covering active employees may not permit the purchase of individual market coverage, even with respect to unused amounts credited to the employee while the HRA was integrated with another group health plan.

### **Transition Relief**

Q&A 3 clarifies the 2013 FAQ Guidance issued on January 24, 2013, by providing that HRAs may reimburse medical expenses without violating ACA's market reforms if the amounts were credited before January 1, 2013, or the amounts were credited during 2013 under the terms of an HRA in effect on January 1, 2013. If the HRA in effect on January 1, 2013, did not set the amounts to be credited during 2013 or the timing of the credits, the amounts credited during 2013 cannot exceed the amounts credited during 2012 and may not be credited earlier or faster than the crediting schedule or rate that applied during 2012.

### **Reimbursing Excepted Benefits**

In Q&A 5, the IRS clarifies that an HRA may reimburse individual coverage that is restricted to excepted benefits only. Such benefits usually include stand-alone dental and/or vision coverage. The IRS is clear to point out, however, that the terms of the HRA must specifically limit reimbursement to excepted benefits. If the terms of an HRA do not limit premium payments for individual market coverage to excepted benefits, the HRA will fail to comply with the ACA market reforms notwithstanding the fact that a covered employee is reimbursed only for excepted benefits.

### **Reimbursing Spouse or Dependent Expenses**

Q&A 4 contains what is likely the most surprising IRS position with respect to HRAs. Specifically, the IRS stated that an HRA is permitted to be integrated with the employer's other group health plan for ACA market-reform-compliance purposes only for the individuals who are enrolled in both the HRA and the employer's other group health plan. Accordingly, if a spouse and/or dependent is not enrolled in the employer's other group health plan, the HRA will fail to be ACA-compliant if funds in the HRA are utilized to reimburse that person's medical expenses. Under a transitional rule, however, the IRS will not treat an HRA and a group health plan that

*The notice provides welcome guidance relating to HRAs that are an integral part of many employers' group health programs.*

would otherwise be integrated based on the terms of the plan in effect on December 15, 2015, as failing to be integrated for plan years beginning before January 1, 2017, solely because the HRA covers the expenses of a spouse and/or dependent who is not enrolled in the employer's other group health plan.

This IRS position is curious since the final regulations, issued on November 18, 2015, specifically provide that an HRA will be considered to be integrated with another group health plan if the employee is "actually enrolled in a group health plan ... that does not consist solely of excepted benefits, regardless of whether the plan is offered by the same plan sponsor." In addition, IRS Notice 2013-54 contemplates that an employee's HRA could be integrated with a group health plan sponsored by his or his spouse's employer. In light of these conflicting sources of guidance and the transitional rule that will render the position stated in Q&A 4 ineffective until 2017, there is ample time for the IRS to clarify its position.

### **Impact on ACA Affordability**

Pursuant to Q&A 7, amounts made available for the current plan year under an HRA that an employee may use to pay premiums for an eligible employer-sponsored plan are counted toward the employee's required contribution for ACA affordability purposes provided the HRA is integrated (as defined in IRS Notice 2013-54 and in subsequent published guidance) with the eligible employer-sponsored plan. Employer contributions to an HRA count toward the employee's required contribution only to the extent that the amount of the employer's annual contribution is required under the terms of the HRA or otherwise determinable within reasonable time before the employee must decide whether to enroll in the eligible employer-sponsored plan. The contribution that meets this requirement relates to the immediately subsequent period of coverage for which the employee could enroll and use the HRA contribution. The employer contribution to an HRA (and any resulting reduction in the employee contribution) is treated as made ratably for each month of the period to which it relates. It is important to note that the employer contribution counts toward the employee's required contribution whether or not the employee actually uses the employer contribution to fund all or a portion of the employer-sponsored plan's premium.

The notice provides welcome guidance relating to HRAs that are an integral part of many employers' group health programs. With the exception of the treatment of expense reimbursements incurred by spouses and dependents enrolled in another employer-sponsored health plan, the guidance in the notice is consistent with previous IRS pronouncements. Employers should review their HRA plan documents and make timely revisions, as needed, to comply with the guidance in the notice.



**Stephen R. Kern**  
*Chair of the Employee Benefits and Executive Compensation group at McNees Wallace & Nurick LLC.*  
skern@mwnc.com

# Enforcement Goes Into Hyperdrive

*In today's stormy risk environment, a strong culture is the safest harbor*

*In their new book, "The New Era of Regulatory Enforcement: A Comprehensive Guide for Raising the Bar to Manage Risk," KPMG's Richard H. Girgenti and Timothy P. Hedley paint a harrowing picture of the unprecedented risks facing companies today. Below, they discuss the enforcement landscape and their prescription for navigating it. Their remarks have been edited for length and style.*

**MCC:** Since your first book, "Managing the Risk of Fraud and Misconduct," came out five years ago, you say we've witnessed a seismic shift in enforcement, resulting in unprecedented risk for companies. What's happened that warrants such strong words?

**Girgenti:** We completed our first book around 2010. The U.S. Congress had just passed, and the president had signed, two pieces of historic legislation: the Patient Protection and Affordable Care Act (PPACA) and the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank). PPACA provided new tools and resources to fight government fraud, waste and abuse in the healthcare industry and made it easier for citizens to bring false claims actions against healthcare providers. Dodd-Frank, the most sweeping financial regulatory reform since the Great Depression, greatly increased the enforcement powers of the Securities and Exchange Commission (SEC) and the Commodity Futures Trading Commission (CFTC). It also created a whole new enforcement agency, the Consumer Financial Protection Bureau, as a watchdog to write rules for consumer protection that governed all companies offering consumer financial services or products.

When these were first introduced, we were just finishing our book and didn't have a chance to assess their impact on the enforcement landscape. During the same period of time, we've seen the bar go up in terms of fines and penalties. Whereas 10 years ago, \$10 million, \$20 million, \$100 million or \$200 million would've been considered extraordinarily large, we've since seen a number of major financial institutions paying fines as high as \$17 billion for some of the mortgage activities traced back to the early days of the financial crisis. We've also seen multibillion dollar fines for U.S. sanctions violations, aiding tax fraud, money laundering and manipulation of interest rates in the Libor scandal. In two heavily regulated sectors, life sciences and energy, we saw a large penalty for unlawful promotion of drugs and failure to report safety data, and almost \$19 billion to settle all federal and state claims over a massive oil spill.

**Hedley:** In addition to the enormous enforcement implications of these major pieces of legislation, it's interesting to consider what companies are being asked to do in light of all these things. Fundamentally, it comes down to ensuring that organizations have done their best to guide the behaviors of the organization, its employees and its agents. In just the last few months, there have been some very interesting developments. For example, the Department of Justice (DOJ), through the Yates memo, seeks accountability from individuals who promote wrongdoing. DOJ has also hired a full-time compliance expert to advise on matters relevant to the prosecution of business entities, including the existence and effectiveness of compliance programs, and it has a new Foreign Corrupt Practices Act (FCPA) enforcement pilot program to promote greater accountability for individuals and companies that engage in corporate crime.

**MCC:** You describe your first book as a broad-based primer on managing fraud and misconduct risks. What's the focus of your new book?

**Girgenti:** It focuses more on the specific areas that have generated a great deal of enforcement activity. We didn't try to chronicle all conceivable risks that resulted from new regula-

*For companies doing business globally, bribery and corruption is the single biggest enforcement issue that they face.*

*— Richard H. Girgenti*



tions and intensified enforcement from legislation prior to the last book. We saw a rise in anti-bribery and corruption investigations and prosecutions. At the same time, we saw an increased focus and enforcement activity in the areas of economic and trade sanctions, anti-money laundering, and offshore tax evasion, as well as increased enforcement in the healthcare and life sciences industries. We tried to focus on those. We wanted to help readers understand the public policies driving this increased enforcement activity, some of the government's expectations for organizational compliance and integrity, the tools and techniques that were being deployed by the government to identify, investigate and ensure organizational compliance, and then help the reader understand the steps that prudent organizations must take to prevent, detect and, as necessary, respond to regulatory enforcement risk.

**Hedley:** Growing out of that focus, we have developed a fundamental framework that organizations can follow to put appropriate and effective compliance programs and policies in place to manage risk effectively and to foster and support a culture of compliance.

**MCC:** What areas of risk do you think threaten the broadest range of companies?

**Girgenti:** Let me start off from the perspective of companies doing business globally. The risk of bribery and corruption is the single biggest enforcement issue that they face. In 2015, we saw slight declines in the U.S. in enforcement metrics. The total number of FCPA enforcement actions brought by the U.S. declined slightly. We also saw a decline in corporate fines. However, it has been reported that there were 126 pending investigations as of December 31, 2015, which seems to be very high. In March of last year, the FBI, in conjunction with the DOJ, established three dedicated international corruption squads, which increased the number of agents assigned to foreign bribery investigations from 10 to 30. In November, the DOJ announced plans to double the size of its FCPA unit by adding 10 more prosecutors. Additionally, the DOJ hired a new compliance counsel to advise on matters relevant to the prosecution of business entities and the effectiveness of compliance programs and, as Tim mentioned earlier, the fraud section is conducting an FCPA enforcement pilot program. On the global level, we're seeing more countries engaged in anti-corruption activity and greater cooperation among the various authorities. We've seen heavy anti-bribery and corruption enforcement activity in Brazil and China, and Mexico and South Korea have adopted new anti-corruption laws and regulations. Add it all up and we see no letup in sight.

**Hedley:** I want to add one more risk area that is common across all listed companies: fraudulent financial reporting. We believe the SEC will pursue more accounting-related enforcement actions. The trends indicate it, and the SEC is devoting more resources to the effort, including the creation of a fraud reporting and audit task force.

**MCC:** Why do you single out two industries, healthcare and life sciences? What special challenges do organizations in these sectors face?

**Girgenti:** In addition to covering risks that primarily impact the financial services sector, such as money laundering and offshore tax evasion, we wanted to examine risks in other heavily regulated sectors. In the healthcare area, the PPACA certainly had a significant impact on the industry, including raising the level of regulatory scrutiny on healthcare providers. With the cost of healthcare escalating and the government one of the biggest spenders, there is heightened enforcement scrutiny on expenditures. We've seen more settlements with extensive monitoring requirements, and it's easier for private citizens to be whistleblowers under the False Claims Act, which allows citizens with knowledge of fraud to bring lawsuits in the name of the government and be eligible for up to 30 percent of the amounts recovered. As a result, in 2015 the government recovered \$3.5 billion of reimbursable expenses – the fourth consecutive year the number hit or exceeded that level.

The life sciences industry has also come under intense government scrutiny for the misuse of taxpayer dollars, particularly in the pricing of products subject to government reimbursement. Other public policy interests, such as the health and safety of patients and transparency and accountability for drugs and medical devices sold to the public, have been drivers of enforcement efforts, spawning settlement agreements with the gov-

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ernment that have fundamentally reshaped business practices and compliance programs in the industry, including unprecedented restrictions on the promotional activities of drug companies.

**MCC:** *You talk about the new tools that government enforcers have at their disposal. How has the state of enforcement changed, and what tools are proving to be especially effective?*

**Girgenti:** I've already alluded to the whistleblower laws. They provide strong incentives to encourage people to report potential violations of federal securities laws or the Commodity Exchange Act. Since the whistleblower program came into effect in August 2011, the SEC has received over 14,000 tips, and this past year, eight whistleblowers received more than \$37 million. It's become a game changer.

We've also seen the use of data analytics and market surveillance. In the same way that the private sector has learned to harness big data to develop business insights and manage risks, so has the government used the same tools and techniques to assist in its identification of potential wrongdoing. An agency such as the SEC is using very sophisticated techniques to investigate such activities as market manipulation and insider trading. The SEC's Division of Economic and Risk Analysis developed a computer model to analyze companies' financial data and uncover indicators of financial reporting abuses. The CFTC also performs broad types of surveillance. Other agencies are right behind them.

There has also been an increase in the use of civil fraud complaints in administrative courts. The SEC has used administrative proceedings to bring many actions that, in the past, might have been brought in federal court. Similarly, the DOJ has relied upon civil fraud proceedings where it once might have considered a criminal action, which creates an advantage for the government because civil fraud cases require a lower burden of proof. And there's been a heightened focus on the prosecution of individuals and gatekeepers. The SEC has talked about going after compliance officers, general counsel and auditors to examine whether they lived up to their responsibilities.

**Hedley:** The increased importance of effective compliance programs, including investigative cooperation, seems to be moving to the forefront. Government enforcement agencies now make it a practice to evaluate not only the existence but the effectiveness of an organization's compliance program. The government will pay particular attention to whether or not there is a strong organizational culture of integrity and whether or not internal controls were properly designed and implemented to ensure that the risk of misconduct in the organization has been addressed.

The challenge for many organizations is there's not a universally accepted definition of an effective compliance program. We believe that our new book will help organizations think about what it means to have an effective compliance program.

**MCC:** *In the book, you lay out a compliance framework for managing the heightened risks arising from the new enforcement environment. What are the key elements of your "common fundamental framework"?*

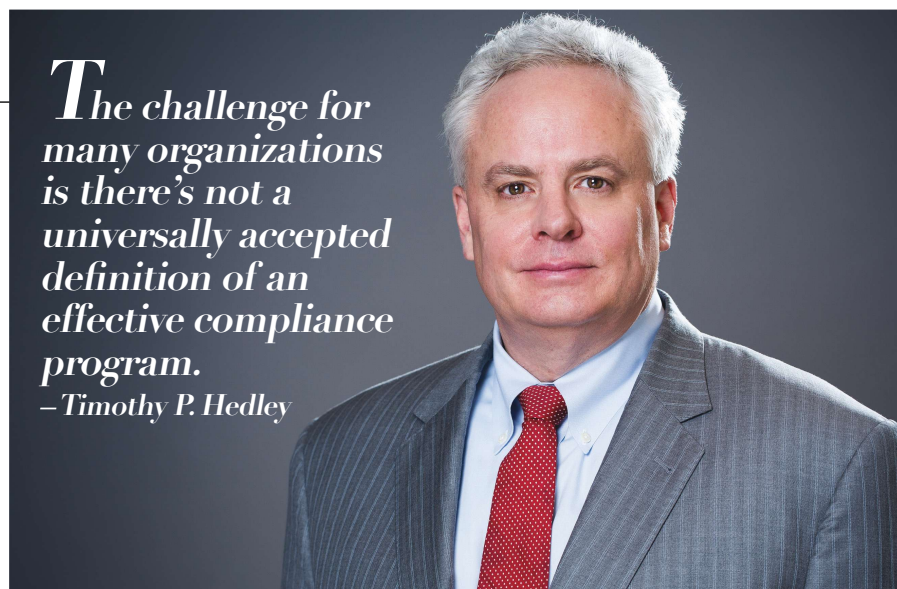
**Hedley:** It is our belief that organizations must design, implement and evaluate policies, programs and controls to prevent, detect and respond to integrity risks. For example, some of the prevention controls would include codes of conduct, which are key to a high-quality compliance program. Also important is the notion of due diligence for both your employees and your agents. For detection, some of these controls would include misconduct reporting mechanisms, such as hotlines. Auditing and monitoring compliance program effectiveness is increasingly important. For response, these would include investigative protocols, reporting and disclosure protocols, and remediation protocols. All of this is supported by what is known as the three lines of defense: management, which is responsible for control ownership; the compliance function, which supports management in that effort; and internal audit, which provides a level of assurance that your program is indeed operating as designed.

**MCC:** *What is the most important thing for companies to do in this new enforcement environment?*

**Girgenti:** If you are going to do one thing, you should work very hard to create and foster a culture of integrity and ethics within your organization. That is the trump card for effective compliance. Organizations that have the right culture are going to be

*The challenge for many organizations is there's not a universally accepted definition of an effective compliance program.*

*— Timothy P. Hedley*



able to deal with the inevitable problems more quickly. If you have the right culture, your organization is going to have a sense of purpose behind it that will make it a stronger and better organization.

**Hedley:** I completely agree. The right organizational culture will help ensure that your employees and agents apply the appropriate ethical values for decision-making. It is hugely important to understand the points of decision at which integrity breakdowns occur.

**MCC:** *Culture is a slippery concept. How do you measure effectiveness?*

**Girgenti:** There are no clear metrics for organizational culture, but as more and more emphasis is placed on it, we're seeing organizations get better at evaluating their own cultures. A lot of it is done through surveys and focus groups where you create benchmarks for things that are indices of a good corporate culture. One of the leading indicators is the willingness of individual employees to raise their hands, along with their level of comfort in speaking up. You can begin to test and measure for that, and it has a direct correlation to whether you have an organizational culture that is strong.

There is also the sense of organizational justice. Does the organization take it seriously enough? Are people, no matter where they are within the organization, appropriately disciplined if they engage in misconduct? Leadership, tone at the top, the openness of communication, the climate, clarity of expectations – these are the kinds of things that organizations are beginning to benchmark against other leading organizations and against results in prior years to see whether they're making improvements.

**Hedley:** I'll add one thing to that. A litmus test of a strong culture is the extent to which people understand their affirmative obligation to report wrongdoing and that they act on that obligation.

**MCC:** *Other than federal regulatory enforcement agencies, are there other levels of government involved in the new enforcement landscape?*

**Girgenti:** It seems like everybody is getting into the game. Perhaps the most significant players today are global regulators and enforcers. Some of the biggest matters recently have resulted from several countries not only cooperating with one another but bringing actions together. Nearly all of the significant anti-bribery and corruption actions that have been brought in the U.S. have an international component. The enforcement landscape is very crowded. We are also seeing state attorneys general, local district attorneys and state regulatory agencies playing a larger role in regulatory enforcement actions. It adds to the complexity of what it takes for a company to see its way through an enforcement action.

**MCC:** *You call the 21st century a "new era of regulatory enforcement." Looking ahead, what will the next era of regulatory enforcement look like?*

**Girgenti:** I think we can say with a high degree of certainty that most of the events that occurred in the past – whether it was 9/11, the financial reporting crisis that followed 9/11, the financial recession in 2008 – were, for the most part, unforeseen. What companies have to do today is prepare for that which may not be foreseen, which means having all of the ingredients of effective compliance and a culture of integrity in place.

One of the things to really keep an eye on right now are the developments coming out of the Panama Papers. Every country has anti-bribery laws, and every country has anti-money laundering laws. Most countries have laws dealing with tax evasion. It seems that despite all of this, there may have been activity in offshore holdings involving politicians and public officials on a massive scale. Like some of the events in the past, organizations, banks in particular, are going to have to look at what they've been doing to see if they missed something. The regulators and the enforcement authorities are also going to be looking at their laws and regulations to determine whether there were loopholes. It wouldn't surprise me, even though I'm not making a prediction here, to see more activity in this area.

**Hedley:** The closest I would get to a prediction is that staying ahead of organizational and individual compliance expectations is not going to get any easier.

# Technology Is a Tool, Not the Solution

## *Successful managed review requires both legal and technology experts*

*Applying analytics to managed review is increasingly familiar territory to RVM's clients. Sanjay Manocha and Shelley Brown describe the importance of their team's relationships in demonstrating the value of analytics to clients who are technology novices, and what corporate law departments can do now to prepare for an efficient managed review down the road. Their remarks have been edited for length and style.*

**MCC:** Please give our readers a brief overview of managed document review's evolution over the past 10 to 15 years.

**Brown:** If you ask five people in the e-discovery industry what managed review is, you'll get five different answers. For some, managed document review consists of staffing a review team with contract attorneys, while others define it as a much higher-level service between a client undergoing electronic discovery and a trusted e-discovery advisor. True managed review is the latter. It is the application of proven, defensible and repeatable best practices, including analytics and top-notch attorneys, to the management of document review. At RVM, we call this process structured review.

The evolution of managed review has followed the growth of big data. Where 15 years ago, smaller data volumes allowed for slower, methodical and even painstaking methodologies, like linear review, the sheer volume of data present in discovery today necessitates a more deliberate approach to uncovering the most important data more quickly. Reviewing everything before discovery closes is often untenable; therefore, managed review today, if it's done well, includes time- and cost-saving strategies and advanced analytics.

**Manocha:** As Shelley was hitting on, one of the biggest changes is a more methodical approach that incorporates analytics within some of the earlier developed tactics, such as batching based on keyword searches or custodians, or even looking at date ranges. Approaches like email threading have come into play. In the past seven to eight years, we have seen analytics being methodically and more acutely applied.

**MCC:** From your perspective, how can corporate law departments best prepare for a managed review, and what should they expect from the team with which they are collaborating?

**Brown:** The very best way that legal departments can prepare for managed review is by having their information governance house in order. Data that ends up in managed review is often dictated by what has been preserved and how well organized that effort is within the corporation. Therefore, an unmanageable volume of data to review is often a symptom of bad information governance.

Another very important step that corporate legal departments can take is to engage trusted advisors before any review begins and to collaborate with that team throughout the process, from collection through production and beyond. They should collaborate with counsel to make sure that the ultimate data set for review is meticulously culled and curated to eliminate any unnecessary expenditures of money or time while ensuring that all relevant data is reviewed.

**MCC:** Managed review requires the use of technology and highly trained experts who can design and execute a thorough and efficient review strategy. What are some of the tactics that you and your colleagues at RVM utilize to provide your clients with the best results?

**Manocha:** Before you drill into specific tactics, it's useful to think about your overall philosophy for analytics-based e-discovery because of the advances in the technology. Analytics has changed nearly all stages of the e-discovery reference

model. However, as Shelley indicated, it hasn't really come of age yet in the information governance space. The earliest we're seeing applications of analytics is to inform the scope of collection in early and targeted fact development, placing counsel in a position where they may potentially enter into a strategic disposition of the matter if they find what they're looking for.

We find a tremendous value early on, to the very left of the e-discovery process, just after information governance and before the broader collection, in a stage that RVM calls Fact Discovery First™. RVM applies analytics early on, before collection and as part of the identification process, and then carries that knowledge through processing and culling. We can apply further refined strategies in the attorney review, relating to tactics that enhance fact development, optimize review efficiencies and enhance the defensibility of the overall process. The overarching concept is that early analytics can set the stage for performance through the rest of the e-discovery process, all the way through to production and even into deposition preparation.

Given that philosophy, one of the tactics we may use is to focus on leveraging analytics in the review process; analytics are very effective at drawing patterns in data. By crystallizing those patterns and analyzing them, counsel can draw inferences from the data that would not otherwise be discernible to a human reviewer. This value-add differentiates RVM tremendously from the average linear review shop.

**MCC:** What are the most important skills or qualifications needed in the review process: project management, a legal background or a technology background?

**Manocha:** We look at the team composition for all matters. Some of RVM's most robust and sophisticated structured review engagements – our technology analytics plus attorney review integration – employ several layers of expertise: typically a consultant, a review manager and an analytics manager. For the most part, all of these people are attorneys with deep experience in litigation and government investigations.

The consultant is a more senior person who demonstrates a strong capacity for exercising good judgment

for relationship building, core communication, technical know-how and crisis management. Crisis management is important because the volume and complexity of engagements and the speed at which e-discovery moves often mimic a crisis situation in which we have to act well and clearly under tremendous pressure. The consultant's role is to be the client's trusted advisor, help the client define the project strategy and coordinate all the necessary resources within RVM's domain to achieve the client's objectives.

The review manager has experience in litigation and government investigations with a focus on all stages of the document review process. Sometimes, he or she will have substantive expertise in the particular subject matter of the litigation or investigation.

The analytics manager, similarly, has had a career path parallel to the review manager's but with a focus on the application of analytics in the various stages of e-discovery. Both the analytics and the review managers work together under the advisement and guidance of the consultant and the client to ensure that the analytics and the review are properly integrated and that the client is getting the full value of those strategies.

**MCC:** When dealing with corporate law departments, how would you describe the roles of technology and people? How do you sell analytics to a legal team that is not tech-savvy?

**Manocha:** The process varies depending on a lot of factors, the biggest one being the volume of the matter. Even the least savvy attorney when it comes to technology and analytics will recognize that if the volume is so compelling, there will be no choice but to use analytics. In those situations, education is significant. We do a lot of panel discussions. We stay involved in the industry, in ensuring that the industry, on a broader level, is aware of how these things can be used.

In situations where the volume of data is not as large, such that analytics is not a necessity, counsel who are not tech-savvy will invariably, unfortunately, choose the more familiar, less risky, linear-based approach. Given the speed at which e-



**Analytics crystallizes patterns so counsel can draw inferences that would not be discernible to a human reviewer.**

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# DOJ's Suit Against Hedge Fund for HSR Act Violations May Clarify the HSR "Investment-Only" Exemption

By Vadim Brusser, Jonathan Cheng & Alexis Brown-Reilly / Weil, Gotshal & Manges LLP

On April 4, 2016, the U.S. Department of Justice (DOJ) filed a civil complaint against two ValueAct entities (the ValueAct Funds) and their general partner (collectively, ValueAct), alleging violations of the Hart-Scott-Rodino Act (HSR).<sup>1</sup> The complaint alleges that the ValueAct Funds inappropriately relied on the investment-only HSR exemption and failed to comply with HSR premerger notification requirements when they acquired shares of Halliburton Company (Halliburton) and Baker Hughes Incorporated (Baker Hughes) in 2014 through 2015.<sup>2</sup> In addition to significant civil penalties of at least \$19 million, the DOJ is also seeking to enjoin ValueAct from any future violations of the HSR Act.

Unlike the recent Third Point "investment-only" enforcement action in 2015, where the parties had agreed to a proposed settlement, ValueAct has publicly stated that it will contest the DOJ's action.<sup>3</sup> Therefore, this action may provide an opportunity for a federal court to weigh in on the limits of the "investment-only" exemption.

Based on the DOJ's complaint and press release, two additional factors appear to have contributed to the DOJ's decision to seek such significant civil penalties. First, the DOJ alleged that ValueAct acquired substantial amounts of Halliburton and Baker Hughes shares (\$2.5 billion in total shares) during the DOJ's antitrust review of the Halliburton-Baker Hughes merger with the intent to influence the merger's outcome. The DOJ has since challenged the Halliburton-Baker Hughes merger.<sup>4</sup> Second, ValueAct had violated the HSR Act on two prior acquisitions in 2003 and 2005; no enforcement action was taken for its 2003 violation, but ValueAct paid a \$1.1 million civil penalty to settle its 2005 violation.<sup>5</sup>

## Background

ValueAct is an activist investor hedge fund that pursues a strategy of "active, constructive involvement" in the management of the companies in which it invests.<sup>6</sup> Halliburton and Baker Hughes are large providers of oilfield products and services around the world. On November 14, 2014, Halliburton and Baker Hughes announced their intent to merge.<sup>7</sup>

According to the complaint, the ValueAct Funds made multiple acquisitions of Halliburton and Baker Hughes voting securities

between November 28, 2014, and June 30, 2015. The complaint also alleged that between November 28, 2014, and June 30, 2015, each of the ValueAct Funds acquired Halliburton shares exceeding \$75.9 million and \$76.3 million, which were the applicable HSR notification thresholds at the time of the acquisitions.<sup>8</sup> Additionally, one of the ValueAct funds acquired Baker Hughes voting securities exceeding \$75.9 million.<sup>9</sup>

However, neither ValueAct Fund submitted an HSR premerger notification form for its respective acquisitions of Halliburton and Baker Hughes shares prior to exceeding the HSR threshold. ValueAct did not make HSR filings on the ground that it qualified for the "investment-only" exemption to the HSR notification requirement. The investment-only exemption applies if an acquirer holds 10 percent or less of the issuer's voting securities and holds the voting securities solely for investment purposes. The acquirer, however, has the burden of showing eligibility for an exemption. In its complaint, the DOJ stated that ValueAct could not rely on the "investment-only" exemption to the HSR notification requirement. The DOJ cited ValueAct's internal communications, communications with investors, communications with executive officials at both Halliburton and Baker Hughes, and public statements to establish ValueAct's lack of investment-only intent.

## Analysis

The HSR Act and HSR Rules provide certain filing exemptions to acquisitions of voting securities that otherwise meet the applicable thresholds. This includes an exemption for stock acquisitions made "solely for the purposes of investment," as long as the acquirer does not acquire over 10 percent of the issuer's voting securities.<sup>10</sup> The HSR Rules limit the exemption by making it available only if the acquirer has "no intention of participating in the formulation, determination, or direction of the basic business decisions of the issuer."<sup>11</sup>

The DOJ cited four types of documents and communications to support the allegations in its complaint that ValueAct lacked an investment-only intent.

First, the DOJ cited draft internal memoranda and internal ValueAct communications among senior ValueAct executives describing ValueAct's intention to influence the management and business direction of both Halliburton and Baker Hughes, including with respect to the parties' merger. For example, an internal communication noted that Value-

Act's share ownership in Halliburton would allow it to influence shareholder approval over the merger.<sup>12</sup>

Second, ValueAct communicated to its investors that it intended to exercise influence over both companies. For example, ValueAct's stake in Halliburton would allow it to be "a strong advocate for the deal to close."<sup>13</sup> Its ownership in Halliburton would also allow it to work with Halliburton's board and management to integrate Baker Hughes into Halliburton's business.<sup>14</sup>

Third, the DOJ cited multiple ValueAct communications with Halliburton's and Baker Hughes' executive management about ValueAct's suggestions regarding the merger and proposed changes in strategy and operations if the merger was not completed. These included proposals to divest certain Baker Hughes business lines, change Halliburton's compensation plan, and offers to assist with merger integration. These communications included emails, written presentations, telephone calls and in-person meetings with both companies' officials regarding these issues as well as other merger and management related topics.<sup>15</sup>

Finally, on January 16, 2015, ValueAct filed a Schedule 13D with the Securities and Exchange Commission, publicly disclosing its stake in Baker Hughes and reporting that "it might discuss 'competitive and strategic matters' with Baker Hughes management, and might 'propose' changes in [Baker Hughes'] operations."<sup>16</sup>

In light of these actions, the DOJ alleged that each of the ValueAct Funds violated the HSR Act by failing to submit timely HSR forms and observe the HSR waiting periods before acquiring Halliburton shares in excess of the \$75.9 million and \$76.3 million thresholds (depending on the time of the acquisitions). The DOJ also alleged that one of the ValueAct Funds violated the HSR Act by failing to submit a timely HSR form and observe the HSR waiting period, before acquiring Baker Hughes shares in excess of \$75.9 million.

The penalties for HSR violations are civil penalties of up to \$16,000 for each day that an acquirer is in violation of the HSR Act. Both ValueAct Funds have sold sufficient Halliburton voting securities such that each fund is currently below the HSR threshold, and the DOJ's complaint alleged violations of the HSR Act for each day the funds held Halliburton voting securities in excess of the HSR notification threshold (without an applicable exemption). The ValueAct Fund that acquired Baker Hughes shares in excess of the

HSR notification threshold, however, presently remains in violation of the HSR Act (at least as of the time of the complaint).

## Commentary

This HSR enforcement action marks the third time in four years the agencies have alleged that certain acquirers failed to file an HSR notification and could not avail themselves of the investment-only exemption.<sup>17</sup>

This matter is still active and could provide for an opportunity for a federal court to define the boundaries of the "investment-only" exemption. Unlike previous enforcement actions that were simultaneously announced with proposed settlements, ValueAct has not settled with the DOJ and has publicly stated its intent to dispute the DOJ's action.

The scope of ValueAct's conduct alleged in the DOJ's complaint appears to be consistent with previous DOJ and Federal Trade Commission (FTC) enforcement actions that rejected the use of the investment-only exemption. However, ValueAct has elected to litigate the HSR violation. Although the federal court may find that ValueAct's actions were consistent with the investment-only exemption, ValueAct's decision not to settle the violation may expose it to a more significant civil penalty and more extensive injunctive relief.

This action may clarify when activist shareholders' conduct may be inconsistent with the HSR rules. The FTC's commissioners were divided on this issue in their recent enforcement action against Third Point, another activist investor. In their recent minority dissenting statement against the HSR violation settlement with Third Point, FTC Commissioner Maureen Ohlhausen and former Commissioner Joshua Wright noted that "[n]ot only is shareholder advocacy unlikely to raise competitive concerns, even if it did, given that the transaction would not raise the unscrambling of assets concern that motivated the adoption of the HSR Act, any necessary remedies can be obtained post-consummation without imposing a substantial burden on either the agency or the parties."<sup>18</sup>

The government's action reaffirms the antitrust agencies' consistent guidance that stock purchasers, including private equity firms and activist shareholders, intending to influence the direction of a business should keep in mind the HSR premerger notification thresholds and filing requirements.

To review the footnotes to this article, visit <http://www.metrocorp.counsel.com>



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# Directors: Be Like Icahn

*Effective boards discipline themselves to think more like activist outsiders*

*In his annual letter to National Association of Corporate Directors (NACD) members, CEO Ken Daly put shareholder activism second on his director watch list for 2016. “Activists aren’t practicing black magic,” he wrote, “they are performing effective due diligence and smart analytics on their holdings. Boards need to think like activists and anticipate the issues these investors may raise.” NACD research director Friso van der Oord here discusses the NACD’s recent report “Director Essentials: Preparing the Board for Shareholder Activism,” which concerns the role of corporate boards in dealing with the rising tide of shareholder activism. His remarks have been edited for length and style.*

**MCC:** NACD has challenged directors of public companies to think more like activist investors. Given that nearly half of them, in NACD’s annual survey, say they are not prepared for an activist challenge, can board members really be expected to think that way? What’s holding them back?

**Van der Oord:** Directors, given their unique oversight role and duty to help maximize shareholder value, should be comfortable in scrutinizing their companies the same way activists do. It’s not a major leap to put on an activist “hat,” and it may make them even better, more informed, board members. Yet there are a couple of real obstacles.

First, there is a real expectation gap about the role of the director. Operating in a part-time role and cautious not to cross the dividing lines with management, many directors oversee their companies at a very high altitude and may miss the warning signals that professional investors are looking for. Good directors often act as effective “devil’s advocates,” but don’t always possess a detailed understanding of the financials and operations of their companies. Moreover, the time commitment for board service has increased significantly over the past five years. The average now is about 250 hours a year. Are directors using that time effectively? Second, they may receive insufficient or highly engineered information from management that prevents them from spotting areas of underperformance. Third, the current committee model may hinder an effective, collective response from the board, as risk factors that attract activist attention may fall through the cracks. The committee structure surely serves a critical role, but it also prevents most boards from getting a holistic picture of how well or how poorly the organization is performing at all levels – operationally, financially, strategically. We often see boards that are run by committee, and that doesn’t help you be holistic in the way activists are. Activists connect the dots very quickly on issues of underperformance and whether your organization is valued properly in the marketplace. The head of the audit committee doesn’t don the activist hat, so to speak, and review their company’s financial statements as an activist would.

There is also a missed opportunity in how board meetings are held. If you look at their agendas, relatively little attention is dedicated to the issues that hedge fund activists are really worried about, such as execution of strategy, the true value of the organization, and underperforming assets. A lot more time is spent on procedural, regulatory issues that in some ways are creatures of a different era – for example, Sarbanes-Oxley compliance.

Effective boards discipline themselves to think more like outsiders and expect sitting directors to offer and articulate that skeptical outsider’s perspective. They proactively ask management to present financial and operational data differently or demand new metrics altogether to help identify underperforming assets. They understand the composition of their company’s ownership, are proactively informed by IR when that composition shifts, and know whether and what types of activists are current shareholders.

**MCC:** When people think of shareholder activism, they think of prototypical activists such as Carl Icahn, Bill Ackman and David Einhorn. But as NACD’s new report on shareholder activism recognizes, activists and activism come in many shapes and sizes, ranging from “light” to “heavy” varieties. Please elaborate on the varieties of shareholder activism and what that means for directors.

**Van der Oord:** Indeed, no company is immune from shareholder activism, but the headline-grabbing attacks by hedge fund activists are relatively rare – it’s a relatively small group – and can be anticipated by tracking the right company performance metrics. It is true that over the last decade, all types of professional investors have become more active – perhaps not activist – including pension funds and the large institutional investment houses, which demand more information from companies they invest in and communications from their respective directors.

We think that approaching the topic of activism with the rigid mind-set that activists are the enemy is misguided. At the end of the day, activists, the board, management and other shareholders want the company to perform as well as possible – they just may disagree about the best way to do it.

NACD has recommended that boards, together with their management teams, adequately communicate their company’s strategy to shareholders and maintain an open dialogue. We believe that directors should make a special effort to stay “communications ready” on topics of key interest to shareholders.

**MCC:** Obviously, declining stock prices and general company underperformance attract activists. NACD’s “Director Essentials” report emphasizes that a deeper understanding of shareholder activism and its evolution will better prepare boards. What’s most important for directors to know as they prepare for what increasingly seems like the inevitable shareholder activism they will face?

**Van der Oord:** While it’s important not to overreact, directors – and perhaps more significantly, the board as a collective – can make formal preparations to mitigate or even prevent the potential impact of an activist challenge. Essential hygiene includes analyzing and understanding your company’s vulnerabilities and what the mix is of those weaknesses or opportunities. For example, do we have underperforming business lines, high cash reserves, low dividends, and potential for sell-offs or spin-offs of business units that are more highly valued separately? Do we have corporate governance practices that are outliers? Moreover, boards should have in place a response plan that addresses how the company may approach specific activist demands and outline a strategy for communicating the company’s response to key stakeholders, including other large investors, the media and proxy advisory firms. It should also build on lessons learned from peers in the industry that have been challenged.

**MCC:** Various studies show shareholders realize sustained gains from activist campaigns. For example, “The Economist” analyzed the 50 largest activist positions in America since 2009 and concluded that, more often than not, profits, capital investment and R&D have risen. Is all the drama around shareholder activism much ado about nothing?

**Van der Oord:** We have observed that the performance picture is somewhat mixed, and it likely may be too early to tell whether activism contributes to long-term value creation and can help companies stay competitive through longer business cycles. Certainly, activists have recorded some big wins and have gained strong short-term returns, perhaps buoyed by the S&P’s post-recession performance. However, the performance of activist funds in 2015 and early 2016, according to the “Activist Investing” annual review from Schulte Roth & Zabel, has been less than impressive, with stocks targeted by activists declining almost 8 percent compared with gains of 1.4 percent for the S&P 500. They are now facing the stern test for any investor in a highly uncertain market: Can they create sustained value and resort less to financial engineering tactics such as share repurchases to artificially boost short-term stock values?

**MCC:** A survey by FTI Consulting shows growing institutional support for activist campaigns. What impact is this apparent support of major investors having on shareholder activism and board response to it?

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**Boards are  
stepping up  
their direct  
engagement  
with the investor  
community.**



# INFORMATION GOVERNANCE INSIGHTS

**By David White**



## Data Laws May Limit Globalization

**T**he confluence of globalization and digital transformation presents many new compliance issues for in-house counsel. One such challenge comes from data localization requirements. As companies become more global, they are also beginning to leverage information to create value in a variety of new ways. From collecting more accurate and detailed performance data to profiling customer needs and influencing decision-making in order to develop or improve products and services, data analysis is helping companies facilitate growth and open up new frontiers for increased revenue. But both the globalization and the digital transformation of business operations require that information flow freely around the world.

With this global growth comes an increasing number of governments that have enacted new regulations restricting the flow of information across their borders. Mainly driven by purported concerns over privacy, security, surveillance and law enforcement, many countries have recently imposed data localization requirements. Unlike the prior generation of censorship controls that typically sought to keep information out of a country, such as the Great Firewall of China,<sup>1</sup> these new data localization controls typically seek to keep data in.

### *Data localization requirements are driven mainly by concerns over privacy, security, surveillance and law enforcement.*

One example is a set of recent amendments to Russia Federal Law No. 242-FZ that went into effect in September 2015. With limited exceptions, this law now generally requires any company that collects personal information pertaining to Russian citizens to “record, systematize, accumulate, store, amend, update and retrieve” such data using systems physically located in Russia.<sup>2</sup>

Similarly, the government of Vietnam recently promulgated several draft laws that included data localization requirements as well as other restrictions on cross-border data transfers. The localization components were eventually shelved. However, as written, they could have potentially required every digital service or website offering services in Vietnam to locate at least one server within that country.<sup>3</sup> The Chinese government also has been considering more regulations with increased localization efforts. The vague State Secrets laws have prevented the removal of certain protected information for several decades.<sup>4</sup> But recently, multiple regulations have been enacted in China that appear to prevent the removal of certain banking,<sup>5</sup> financial,<sup>6</sup> and personal health information<sup>7</sup> from within its borders. Restrictions in other industry sectors in China also appear to be under consideration. Most recently, a draft counterterrorism law was circulated in 2014 that, if enacted in its original form, could have potentially required business operators in the Internet and telecommunications sectors to store data on servers in China and provide encryption keys to public security authorities.<sup>8</sup> While this law was passed without these localization requirements, the possibility of laws with similar restrictions being passed in the future still remains. The list of countries that have data localization laws under consideration,<sup>9</sup> or that have recently enacted or considered them, continues to grow around the globe.<sup>10</sup>

Inevitably, the collection and usage of customer personal data brings about challenging questions regarding data protection and usage. As companies expand their markets and move to digitally transform their operations, they must fully consider both the sources and subject matter of the data they are collecting and the various laws and regulations that apply to them. Privacy laws are typically triggered by the residence and nationality of the data subjects, not simply the location of the data or its collection activities. The questions can be complex, but to avoid compliance gaps, company counsel should begin making the effort to map their data supply chains, fully understand their contents, and align them with the privacy laws of each jurisdiction they may implicate.

The opinions expressed are those of the author and do not necessarily reflect the views of AlixPartners, LLP, its affiliates, or any of its respective other professionals or clients. To review the footnotes to this article, visit <http://www.metrocorp.counsel.com>

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**Van der Oord:** Certainly, institutional investors welcome activists who help force boards to sharpen their strategic focus and can help catalyze necessary changes in companies, but increasingly, many of the large asset management firms are concerned that even the threat of activism prevents firms from taking a long-term approach to value creation and may come at the expense of long-term shareholders. This was exemplified by the recent news in the Financial Times and other major news outlets that Berkshire Hathaway CEO Warren Buffett, JPMorgan Chase’s Jamie Dimon, and BlackRock chair and CEO Laurence Fink have been meeting privately since August of 2015 with heads of the world’s largest asset-management firms to advocate for a stronger focus on long-term value creation. In an open letter to the CEOs of the S&P 500 companies, Fink wrote that activist investors’ demands for short-term profits could lead boards to conduct “potentially destabilizing actions.” Instead of concentrating on minor deviations from analysts’ earnings expectations, companies should use quarterly reports to show progress made in executing long-term strategies.

**MCC:** *In 2014, Vanguard announced that it would propose “shareholder liaison committees” to the boards of companies in which it is invested. This sparked a lot of discussion about shareholder-director communication. What’s the state of shareholder engagement? Are things moving in the right direction?*

**Van der Oord:** I do think boards are stepping up their direct engagement with the investor community. Every year, the NACD solicits perspectives from the investor community – including the large institutional investors – about this issue, and they observe real progress in board engagement and communications. In our recent director survey, more than 40 percent of respondents indicate that their board met with institutional investors in the past 12 months. Major investors report that they are seeing the quality of dialogue continuing to advance and improve. Conversations are a lot more integrated, with issues like board composition and executive compensation now clearly tied to companies’ strategic objectives. They also noted that more directors are getting to know their companies’ top shareholders, and that discussions now offer more understanding of how board members at specific companies view their role.

**MCC:** *Many shareholders say the information they get from discussions with directors is especially valuable. Yet many directors are passionately against the idea of engaging directly with shareholders, citing concerns over Regulation Fair Disclosure and/or that investor relations is not their job. How do you respond to that?*

**Van der Oord:** Reg FD applies squarely to any communication between a director and a shareholder. Indeed, some directors and board advisors have pointed to Reg FD as a key reason to avoid any and all exchanges between directors and shareholders. However, SEC staff guidance published in 2010 makes clear that directors are not prohibited from holding private meetings with shareholders and provides useful tips for conducting such meetings without running afoul of Reg FD. For example, make sure that directors are trained and authorized to speak on behalf of the company and only entertain private discussions with investors or groups of investors. Additionally, topics for discussions should be pre-cleared and, in certain instances, it makes sense to have company counsel and/or investor relations participate in these meetings.

In general, NACD recommends companies have a board-shareholder communication policy, with a section that focuses particularly on abiding by Reg FD, to lay the groundwork for these discussions. This policy should specify which board members, if any, are permitted to engage directly with investors.

# Hallmarks of a Successful Deal

*Frontier's recent acquisition offers a road map to M&A planning and execution*

**Mark Nielsen**, general counsel of **Frontier Communications Corporation**, outlines his role as the in-house lawyer for M&A evaluation and execution, as well as provides his reflections on Frontier's recently completed transaction with Verizon Communications. The acquired businesses include approximately 3.3 million voice connections, 2.1 million broadband connections and 1.2 million Fios subscribers. His remarks have been edited for length and style.

**MCC:** Please describe the recent transaction with Verizon.

**Nielsen:** Frontier Communications acquired Verizon's operating subsidiaries in California, Texas and Florida for \$10.54 billion in cash and assumed debt. The transaction doubles Frontier's size – to approximately \$11 billion in annual revenues – and brings the company within the ranks of the Fortune 300. From a relatively small, rural telephone company in 2009 with annual revenues of approximately \$2 billion, Frontier has transformed itself through a series of three transactions (in 2010, 2014 and now 2016) into one of the largest communications companies in the United States.

Our transaction with Verizon involved enormous complexities – legal, regulatory, financial, technological and operational – and I am proud of the critical role Frontier's legal department played in each of these areas. The transaction was truly a massive team effort.

**MCC:** Can you break that down to the specific components for us, starting with the strategic picture?

**Nielsen:** To be successful, a transaction must align closely with the company's overall business strategy. The business operations that we have acquired from Verizon are a core business for Frontier, utilizing our core competencies as a company. Frontier has a different business strategy than Verizon, so this transaction clearly made sense for us. Frontier can operate a wireline video, broadband and voice business at significantly lower cost – particularly lower overhead cost – and we are expert at maximizing the value of legacy copper wireline properties while also being highly capable with fiber optic networks. In fact, Frontier has a new product, Vantage TV, that allows us to deliver high-quality video efficiently over existing copper networks, which is much less capital intensive than putting fiber optic cable in place everywhere.

In addition to playing to our core competencies, the transaction is beneficial from a tax perspective. It is structured as a stock deal with an IRC Section 338(h)(10) election. This means that the acquisition will be treated as an asset purchase for tax purposes, with the accompanying tax benefits resulting from higher depreciation following the write-up of the acquired assets.

**MCC:** With a value-adding transaction identified and structured, what steps were needed to get the right deal negotiated?

**Nielsen:** One of the first things we did was to carefully consider the lessons learned from our prior major acquisitions, including the 2010 deal with Verizon covering its wireline service territories in 14 states and our 2014 deal with AT&T covering Connecticut. This was an important first step for us.

It is absolutely critical to have the right people in place. On the in-house side, I had brought Jeff Conner into Frontier's legal department as my deputy general counsel. Jeff has 25 years of experience in high-level M&A, corporate finance and securities work, including the prior 10 years at Dole Food Company. He provided critical counsel on some challenging issues throughout the transaction.

For outside counsel, I hired one of New York City's preeminent law firms, and we worked to establish an appropriate working relationship with the firm. It is vital that outside counsel understands that it takes its direction from the company's legal department. Outside counsel must not see itself as controlling the deal or controlling the negotiation of the deal – and this must be made clear at the outset.

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**A key driver is continuous consultation with the business leaders about which issues are most important or contentious, and why.**

Another key driver of success is continuous consultation with the relevant leaders in the business about which negotiation issues are the most important or contentious, and why. However well informed the lawyers may be on a deal, they will never know as much about the business as the operational leaders. These leaders must be comfortable with the content of the representations and warranties, covenants (especially operating covenants effective between signing and closing), schedules of included assets, ancillary agreements, and the like.

Also important to the success of the deal is the character, depth and quality of the due diligence effort. This is critical not only to assess the value of included or excluded assets and liabilities but to adequately understand the specifics of the acquired business well enough to plan the integration effort and successfully run the business after closing. For these reasons, the company's business people, in addition to its lawyers, must be intimately involved in the due diligence effort.

Lastly, in a transaction like ours with more than a year between signing and closing, the operating covenants must be very carefully considered. Our focus in this regard was to ensure that the Securities Purchase Agreement and the ancillary agreements gave both parties the proper incentives to play it straight and avoid self-advantaging behaviors preclosing. This had the intended consequence of minimizing wasteful defensive behaviors so that both sides could focus on completing the transaction as swiftly and efficiently as possible.

**MCC:** What do you regard as a key lesson concerning the financing efforts in making the transaction a success?

**Nielsen:** Frontier financed the acquisition through a combination of a registered offering of common and convertible preferred stock, a delayed-draw Term Loan A, and a Rule 144A offering of three series of unsecured senior notes. Frontier was very proactive in getting the financing done, to the point that we had completed the financing six months before the closing. By being so proactive, we eliminated any financing risk, pressure and distraction, allowing management to focus on integration planning and implementation, as well as running our existing businesses.

**MCC:** Could you comment further on Frontier's integration efforts?

**Nielsen:** Frontier put an enormous effort into integration planning and execution. It was almost like the moon landing. We invested time and resources on each aspect – operations, technology, human resources/labor and employee relations, government relations, tax, public and investor relations, marketing and customer communications. Frontier's integration effort spelled out every needed step, small and large, and assigned responsibility for each one. This planning effort included not only the optimistic case but also contingency planning in the event that problems arose. We worked to anticipate both preclosing and postclosing issues.

The integration involved many departments and sub-departments in both Frontier and Verizon. In the 14 months between signing and closing, we dealt with innumerable issues with Verizon. Under these circumstances, we understood that frictions could easily arise. We appointed the head of our integration team as our senior contact person with Verizon, and Verizon similarly named a senior contact person on their side. All disputes beneath this top level were not allowed to fester but instead were expeditiously elevated to the one-on-one top relationship for efficient resolution. This process ensured that we established and maintained a cooperative partnership. It was highly successful, as it should have been, since after all, the transaction was desired by, and in the best interest of, both Verizon and Frontier.

I received a note the other day from the head of Frontier's integration team, offering thanks for the positive role played by what he referred to as the "friendly lawyers" from Frontier's legal department. Too often it seems that lawyers are seen as those who say no and obstruct things that need to get done. He was commenting that the lawyers in Frontier's legal department were, instead, constructive, helping him get to yes with Verizon and solving a number of complex integration issues and challenges. His note represents a major achievement for our legal team and positions us as solid business partners – precisely where we need to be in order to give our best counsel.

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# Temporary Status as an Interim Solution

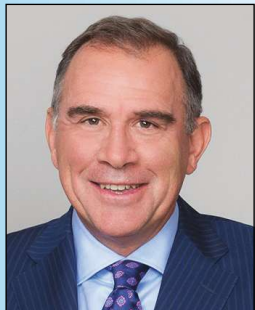
*Employers look to TPS to expand their pool of foreign nationals authorized for work*

The Supreme Court is currently deciding whether the president's executive action granting Deferred Action for Parents of Americans and Lawful Permanent Residents (DAPA) is constitutional. If the Supreme Court finds in favor of DAPA, it would provide a three-year reprieve from deportation for millions of foreign nationals, which would also allow those foreign nationals to obtain an employment authorization document (EAD). In the meantime, employers should know that there are other programs available for foreign nationals that offer similar benefits and may serve as great opportunities for employing foreign nationals authorized to work.

Specifically, temporary protected status (TPS) is a temporary immigration status granted to individuals in the United States who are from designated countries undergoing armed conflict, environmental disasters or other extraordinary and temporary conditions. Although TPS has been in existence since 1990, it has been authorized in only 22 countries, and the majority of these countries have been authorized in the past three years. Similarly to DAPA, individuals granted TPS are eligible to apply for work authorization and permission to travel abroad for short periods of time. Overall, as TPS has been extended to more countries and DAPA remains undecided, employers should be aware of their ability to employ TPS individuals who have an EAD.

As TPS has become much more prevalent in the past three years given the natural disasters, health emergencies and political turmoil around the world, employers should be aware that several countries are now TPS designated. This has greatly increased the pool of foreign nationals who are TPS work authorized. In 1999, only Nicaragua and Honduras were designated for TPS. However, since then, 20 additional countries have been authorized. Specifically, the following 13 countries have been designated for TPS since these dates: Nicaragua, January 1999; Hon-

duras, January 1999; El Salvador, March 2001; Haiti, July 2011; Somalia, September 2012; Sudan, May 2013; Guinea, November 2014; Liberia, November 2014; Sierra Leone, November 2014; Syria, January 2015; Yemen, September 2015; Nepal, June 2015; and South Sudan, January 2016.



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Further, although TPS is technically a temporary status, in recent years, the Department of Homeland Security has issued automatic extensions of employment authorization for TPS recipients from certain countries. More specifically, these automatic extensions are successive, which is why such countries as Nicaragua and Honduras have been continuously authorized since 1999. The automatic extension typically extends the authorization for six months, but the time period can vary. Additionally, it is rare for a country to have its TPS designation terminated. Since TPS originated, 22 countries have been designated and only 9 have been terminated. Notably, the last TPS termination was Burundi in October 2007.

For purposes of employer Form I-9 compliance, it is also important to note that employers must accept a TPS EAD that is expired on its face if in fact the government has extended EADs for that TPS group. As such, if the EAD is expired, or is approaching expiration, employers should reference the United States Citizenship and Immigration Services website or the Federal Register notice regarding the appropriate country to determine whether the government has granted an automatic extension; if so, then the person with that EAD remains authorized to work.

It should be noted that if a foreign national presents a valid EAD, the employer must accept the valid EAD (unless it does not appear genuine or to relate to the person presenting it). Additionally, when complying with I-9 verification, individuals with TPS may choose to present other acceptable documents for initial Form I-9 verification or reverification purposes. As such, if an employer requests more or different documents than are required by the I-9 process, the employer may violate the anti-discrimination provision of the Immigration and Nationality Act (INA).

Lastly, although TPS does not automatically lead to lawful permanent residence (a green card) in the United States, a TPS grant does not preclude individuals from obtaining other immigration statuses for which they may qualify. In addition, in a recent case, *In Matter of Arrabally and Yerrabelly*, 25 I&N De. 771 (BIA 2012), the Board of Immigration Appeals described the process by which certain individuals with TPS could adjust their status to lawful permanent residence. Specifically, a person who enters the United States without inspection and is subsequently granted TPS can cure their unlawful entry by departing the United States and then reentering through a mechanism called advanced parole. Doing so means they will not be subjected to the 10-year bar, which is normally triggered by a departure after having been in the United States illegally for longer than one year.

Danny Alicea, Fragomen fellow; Pamela Frederick, law clerk; and Nancy Morowitz, counsel at the firm, assisted in the preparation of this column. To learn more about Fragomen, please visit <http://www.fragomen.com>

## Successful Deal

*Continued from opposite page*

**MCC:** You had to obtain federal and state regulatory approval before the transaction could close, and as a public company dealing directly with millions of residential and business customers, you had to deal with investor and public relations. What were the main challenges in these areas?

**Nielsen:** That's right. We had to obtain federal antitrust clearance under the Hart-Scott-Rodino Act. We also had to obtain approval from, among others, the Federal Communications Commission and the utilities commissions in California and Texas. These are very effort-intensive undertakings. The regulatory authorities are appropriately interested in understanding, at a very detailed level, the many aspects of the transaction to ensure that affected constituencies, and the public overall, will be protected. We worked very hard to make that case – to meet with, engage in negotiations and ultimately enlist the support of the many interested constituencies – in a fashion that was mindful of their legitimate interests and also of our need to be in a position to run an efficient and profitable business postclosing.

Concerning investor relations and also public relations, which reports to me, we adopted what I firmly believe is the only sustainable principle: transparency. We worked to give realistic estimates of, for example, anticipated synergies, and we

updated those estimates as we received better and more complete information. We were clear and direct on projected accretion to free cash flow per share and on the projected reduction in our dividend payout ratio.

On the public relations side, we introduced ourselves to our new customers in a straight and respectful way, without hype or overpromising. And when a number of operational problems occurred immediately postclosing, we responded quickly in easy to understand terms with as much information as possible. We said what we knew and what we didn't know. We explained why there were service interruptions, identified the cause and gave an estimated time for service restoration if we knew the information. I am a big believer that today's consumers are very sophisticated and appreciate it when a company just levels with them. With the influence of social media, companies must respond quickly, honestly and frequently.

**MCC:** Any final thoughts?

**Nielsen:** I am very proud to have been part of such a magnificent team effort, under superb leadership at the top of Frontier, and I am equally proud of the people on my team for their outstanding professional service during this complex, difficult and enormous undertaking. This is a transformative transaction for our company that helps put Frontier on a path to sustainable growth – a win-win for our employees, customers and shareholders.



# Change is More Than Just Talk at Panasonic

## *Creating a culture of compliance and collaboration*

*Rapid turnover in the C-suite, full-blown proxy fights, merging business cultures – Panasonic's GC Damien Atkins has borne witness to it all. He discusses his M&A successes, and one pivotal failure, along with his plans for Panasonic's in-house operations and how to face global compliance concerns. His remarks have been edited for length and style.*

**MCC:** Congratulations on being included in the list of the "Top 100 Most Influential Blacks in Corporate America" by "Savoy." I understand the magazine received over 500 nominations.

**Atkins:** Thank you. It was particularly gratifying because it recognizes African-Americans who not only have made an impact on corporate America but who have also contributed to the betterment of their communities.

**MCC:** Tell us a little about yourself and your background.

**Atkins:** I'm originally from Oakland, California. My father joined the Foreign Service when I was young, so a lot of my boyhood years were spent in Ecuador, Panama and a number of other countries. After graduating from Banneker High School in Washington, D.C., I received a B.A. from Stanford, then moved back east to attend NYU law school.

Upon graduation, I joined the corporate department of Chadbourne & Parke, left it to join an Internet startup, govWorks, then returned when, nine months later, the dot-com filed for bankruptcy. Sometime in my seventh year, I left again, this time for good, to join the legal department of AOL as a junior member of its M&A team, eventually becoming vice president, responsible for M&A, corporate governance and real estate matters. I stayed with AOL through its spin-off by Time Warner and the relocation of its headquarters from Northern Virginia to New York City. About a year ago I joined Panasonic USA.

**MCC:** That must have been an interesting time to be at AOL.

**Atkins:** Absolutely. I think we cycled through three CEOs and as many general counsel during my time there. But I would not trade that experience for anything. I got to meet some really top-notch people who showed me what it means to be an excellent general counsel – and, quite frankly, an excellent leader. Folks like Julie Jacobs, the current general counsel, who's been with AOL since at least 2000; her predecessor as GC, Ira Parker, with whom I still communicate on a fairly regular basis for insight; and Tim Armstrong, AOL's current CEO and a former president of Google America's operations. Great people, great industry, just an all-around great experience.

**MCC:** Can you talk about some of the changes you've brought to Panasonic and its in-house legal operations?

**Atkins:** I would have to start with the compliance program. Compliance in North America is very, very decentralized, and Panasonic felt that it was time for someone to take a fresh look at it. What are we doing right? What are we do-

ing wrong? How can we make this a best-in-class program? We've already changed our messaging and training. Ling-Ling Nie, Senior Counsel and Director of Compliance and Ethics, has been leading the charge. She's done some pretty out-of-the-box things, like having a former convict come in and speak to Panasonic employees about what can go wrong when you don't have a culture of compliance. Our focus now is on how to measure the effectiveness and impact of these changes.

In terms of how the legal department functions, we've implemented some changes that may sound small but have had a very large impact on how our team performs. One involves recruiting and hiring. Unlike the usual law firm or legal department interview process where you meet someone, you talk for 30 minutes, you check a box and, voilà, they're hired, we've started using DiSC personality assessments and skills tests that go to core competencies. For example, a day before the final interview, we might dump a lot of data or a contract on a candidate's desk and ask him or her to create a five-page PowerPoint, present it to a group of executives and be prepared to answer questions.

We're also about to roll out a new electronic billing system, we've beefed up our in-house M&A capability and, I know this doesn't sound sexy, but we're undertaking some organizational changes, chiefly in terms of scalability, to ensure that the department will be a better fit for where Panasonic sees itself in two or three years.

**MCC:** Have you considered bringing in non-lawyers, such as MBAs or procurement specialists?

**Atkins:** There are certain critical skills that, if you look at where the business is today and where it's going, we lacked when I got here. We're a player in solar power generation. But while the firm has solar project finance teams, we didn't have the in-house legal capability to support them, so we brought someone in to take care of that.

The challenge is figuring out what is our baseline level of performance from an operational perspective. What are the key processes and procedures that we do on a day-to-day basis, and how can we do them better? You start off by mapping those processes. For example, what is our process for responding to subpoenas, and is it the best way? Our deep dive into process includes looking at outside counsel spend. How many attorneys at how many law firms are we working with, and are we working with them effectively? E-billing will allow us to have a baseline and to make year-over-year and even quarter-over-quarter comparisons.

**MCC:** Are there any personal accomplishments that you'd like to highlight?

**Atkins:** It's not really my own personal accomplishments, but I do take great pride in watching people who are given authority and space within which to work and grow, exceeding expectations.

We had a very flat structure when I joined. Everyone reported to the general counsel for the most part. There was no leadership team so to speak. I've put certain people in key leadership roles. For a lot of them, it's been their first time as a leader, and seeing them develop as leaders has been a very pleasant experience for me. At the end of the day, the goal of any leader is, or should be, to find one's own



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**Seeing the organization grow stronger by unleashing people's talents is very gratifying. The more employees involved in changing a process, the more they have a stake in its success.**

replacement. Seeing how the organization has grown stronger simply from the unleashing of people's talents has been very, very gratifying.

**MCC:** *What have been some of your greatest challenges and how have you overcome them?*

**Atkins:** Panasonic is a 100-year-old company, which has been in the United States since 1959. For most of its history, its primary focus was on shipping products made in Japan for sale to U.S. consumers (or sometimes B2B, in the case of its industrial products). As a result, the entire organization's processes, as well as the mind-set of its people, have evolved to optimize the achievement of those goals. So the biggest challenge has been working with folks who have done the same thing for an extended period of time, who know the world has changed and the company is changing but don't know (and fear finding out) the impact of these changes on their own roles. Making the change-management process as smooth as possible has required a lot of over-communicating, a lot of saying over and over again, "We have to be open to change. Some hard choices may have to be made. But at the end of the day, we'll all be better and stronger for it."

It's also required a lot of humility on my part because while I have a good sense of where our department needs to go, I also know that I don't have all the right answers, and that my way may not necessarily be the best way. As long as things are headed in the right general direction, I have to be open to making adjustments and to remember that the more employees who are involved in the change process, the more they will have a stake in its success. So I encourage them to speak up if they see me veering off the path or a boulder ahead that isn't on my radar.

**MCC:** *You're very well-known for your expertise in leading mergers and acquisitions, and for managing corporate governance. Can you share some of your experiences in these areas?*

**Atkins:** I've handled both big and small M&A deals, but curiously, it's usually the smaller transactions that end up resonating the most. One major deal that comes to mind is actually one that didn't work out well. It was 2007 or 2008, and I was at AOL. We were trying to buy a Swedish online advertising firm. We were offering almost \$1 billion for it, but at the end of the day, it was rejected. My sense was that the rejection was not for purely business reasons; there were also some political and nationalistic reasons involved. Being over in Stockholm in January, working through the peculiarities of Swedish anti-takeover law and various other cultural issues and then, after all that, the deal not going through...that more deals fall apart than actually get done is a humbling lesson that all M&A practitioners eventually learn. That was my rite of passage. All that time in Europe, all those complex issues, and then one day, seemingly out of nowhere, it all gets blown to pieces.

In the corporate governance area, I recall while at AOL winning, against all odds, a full-blown proxy fight. I think it was the first time this particular activist investor had ever lost a proxy fight. Living through that experience, which went on for seven or eight months, was really transformative for me because of how closely I was working with the board of directors, as well as with outside counsel, proxy solicitors, communications professionals – all these cross-functional teams toward the same goal. And you don't know if you're going to win or lose until the day of the annual meeting.

Another corporate governance highlight was working with so many top-notch, high-intelligence, highly driven, extremely experienced AOL board members, such as Jim Stengel (a former global marketing officer for Procter & Gamble), Hugh Johnston (executive vice president and chief financial officer at PepsiCo), Eve Burton (the GC of Hearst), Alberto Ibargüen and Fredric Reynolds (a former CFO of CBS), among many others. Being there at the beginning and seeing these individuals with their unique skill sets, outlooks and experiences come together to form what, in my view, was one of the best-functioning boards in the country was quite an education and something I still think about frequently.

**MCC:** *How do you go about ensuring legal and regulatory compliance across Panasonic and all of its affiliates?*

**Atkins:** Unlike AOL, which was smaller and much more centralized – while it had subcultures, like the Huffington Post, you could still have a unified and strong compliance program – Panasonic USA is very decentralized, very siloed, and the

nature of the businesses it is engaged in are radically different. Consequently, ensuring compliance does not lend itself to a "one size fits all" approach.

Panasonic Avionics Corp, for example, has a singular focus – customized in-flight entertainment and communications solutions – and operations in 30 countries. Panasonic Enterprise Solutions Co., on the other hand, is a conglomeration of disparate businesses, ranging from a unit that develops large-scale solar energy systems to one that installs large video screens and scoreboards at sporting and entertain-

ment venues. It operates primarily in North America. Panasonic Avionics has its own compliance officer with global responsibility – Rob Lindquist – who, being so close to the business, has done a fantastic job of tailoring a compliance program that works really well for it.

Add to that the fact that we are also a subsidiary of a Japanese corporation. If you look at Panasonic as a whole, there are certain global compliance concerns that have to be integrated to each one of these different businesses. So whether it's antitrust, anti-bribery, those kinds of things, those have to be another one of the cornerstones around which you design the program. And they might not necessarily be priority number one at some of these smaller businesses, but you have to do it because we are a part of that global company.

Being a subsidiary of a Japanese company, the approach to compliance varies considerably geographically and culturally on a global basis. So in North America, the change has been more on business ethics, creating a culture of compliance, messaging, ethical awareness. Whereas in a lot of places, in Japan, Europe and elsewhere, it tends to be much more based on training, which is equally important. It's harmonizing the two approaches for something that makes sense, not only just for the U.S. businesses but also as part of an integrated multinational Japanese corporation.

**MCC:** *What advice would you give to new general counsel looking to improve their in-house legal department?*

**Atkins:** First, your success is dependent upon your best people and your worst people, your high performers and your low performers. You're only as good as your people, so make sure that you have your best people in the highest impact, most critical roles, and deal with your lower performers as quickly as possible.

Second would be understanding what the value equation is for an in-house lawyer. What I mean by that is lawyers are trained to believe that I'm adding value because I am satisfying or finishing or completing a set number of stated legal tasks or functions. "Draft me this complaint, file this lawsuit, manage costs," and so on. But the true measure of value is what I call third-eye skills, or taking care of the unstated or unknown needs of clients. The only way to really do that is to know the business as well, if not better than, your client.

Be humble and understand that you don't know everything, so you have to approach everything with a child's mind and be willing to learn as much as possible and listen. It's amazing how much you can learn and find out about your clients and what their issues are that they might not even be aware of just by sitting back and listening. It's understanding that how you add value has very little to do with how busy you are. It's really what impact you are having on the business. Are you increasing revenue? Are you increasing profitability by cutting costs? Are you bringing new business to your clients? Otherwise, they can just put anyone in the chair to do legal work. Understanding that to truly, truly add value and understanding how the value equation works would be my biggest set of advice.

**MCC:** *Are there any individuals or books that have inspired you and helped you develop personally or professionally?*

**Atkins:** Wow, funny you say that. Aside from my parents, one individual is probably my grandmother. She's been a great inspiration to me. She passed away a couple of years ago, but she started off her career as a librarian. Somehow, some way, she decided to enter politics in Oklahoma back in the 1960s and became secretary of state and held various other positions. She was very active politically in Oklahoma in the '80s.

In terms of books, one that I'm reading now that is extraordinarily helpful is "You Gotta Have Wa," by Robert Whiting, which examines the differences between American and Japanese culture through the prism of baseball – I have not been able to put it down. Another book would be "The Truth About Dishonesty" by Dan Ariely. If you're looking at changing a compliance program, anything written by Dan Ariely is very, very helpful.

# A Portal to Action

*UBIC's business intelligence tool lets customers control their project's destiny*

**V**ia UBIC's Trust Business Intelligence Portal, companies can extract metrics regarding the data they generate to make more informed decisions about staffing, spend, and work flow, both for existing matters and as a historical comparison.

**Shamir Colloff**, CTO at UBIC, describes how the portal has benefited his customers in a variety of ways: reducing email traffic, assessing spend versus hours required, providing common ground between legal and IT departments – even helping UBIC's own evaluation of the quality of its project management teams. His remarks have been edited for length and style.

**MCC:** Please give our readers a brief overview of your career in the legal technology space.

**Colloff:** I started out in this business at Morrison & Foerster, first as a paralegal and then in the Practice Support group, managing e-discovery for large intellectual property (IP) and patent litigations in the Silicon Valley office. Through good luck and connections, I met Andy Jimenez, who was running Evolve Discovery. I joined Evolve Discovery, which has since been acquired by UBIC, as its first director of technology and am now CTO. I've been here nine years this December.

I take a consultative approach with customers over how to best use technology for their matters. As of late, I've been very focused on business intelligence and how to provide our customers insight into what data they have and how to best use what they have.

**MCC:** UBIC has a unique product called the Trust Business Intelligence Portal. What is business intelligence, and what business problems can it solve?

**Colloff:** Fundamentally, business intelligence is the ability to extract meaningful information from the data that clients generate. We use that data to make more informed decisions that are actually representative of what's happening on projects, what we're spending, and what we're doing.

We keep track of, for example, how many users they have on the database, how many hours we're spending on their projects, how many hours their document reviewers are spending on their projects. The Trust Business Intelligence Portal gives our clients insights and visualizations into their usage.

**MCC:** How can the portal help in-house law departments develop more effective work flows and manage costs?

**Colloff:** The portal gives clients the ability to see across the enterprise, and also to drill into an individual project or type of service. They can see how they're spending their money, either with us or third parties, and use that information to find anomalies and patterns in their data sets.

There's also a real-time status update function, giving customers a window into our project management organization. They can see the tasks we have in our hands, the status of those tasks, and when we expect to be done with them, and they can track all the communications that have happened around those tasks. This is the meat and potatoes of the portal, allowing customers to become a part of the project management team. One plain and simple benefit is decreasing email traffic. No one likes sending emails to get status updates, and no one likes fielding emails about status updates. The ability to log in and get self-service, real-time status updates on demand puts more power into the hands of the people writing the checks.

Another way that the portal can help in-house legal departments is to compare on an apples-to-apples basis their usage and consumption across different projects with similar legal profiles. Say, for example, a corporation has a portfolio of employment litigation, a portfolio of IP litigation, and maybe one bet-the-farm case every few years. Our system lines up all of the IP cases next to each other, and the client can see pie charts that reflect, for example, how many users were assigned to each of those cases, how many hours were spent, how many gigabytes were processed. It gives them the ability to take a data-dependent approach in how they select, vet and manage their outside counsel.

There are practice group leaders saying, "I want to know how we are doing across all of the cases I run. Where are we doing well? Where could we improve? What are our



**It's a race to who is going to be first to understand their data and use it to make decisions.**

strengths and efficiencies?" It's a race to who's going to get there first, to understanding their data and being able to use it to make decisions.

**MCC:** What do clients like about the self-service feature?

**Colloff:** It gives them the ability to get an update on a request immediately. They log in to the system, and there's the update, with the history of what's happened, where we are in the process and our estimated time to completion. Empowering them to get real-time updates gives them the ability to more effectively manage their projects.

We used the tool recently for a firm that had a very large case with us – 500-plus custodians – and there were dozens of requests a day, hundreds of requests a week. At the outset, there was a lot of email, and once we converted the firm to the portal, they only sent an email when they said, "I want to change the priority order. I need to do this immediately, even though

I know you're doing something else now." Our team was no longer spending a lot of time with back and forth, which wasn't helpful for the customer or for us either.

**MCC:** Analytics are key to risk and litigation management. How can this portal help in-house law departments develop the analytics that they need?

**Colloff:** A lot of the sections in the portal have title headers that start with KPI: key performance indicator. Frankly, KPI isn't something that a lot of folks in the legal field have experience with, nor is it something, when you're practicing law, you really have to worry about for now. But we're trying to distill the usage, spend and work detail down to specific data points that can be repeatedly measured against. A corporation can look at how many users on average should be on a database, how many pages should be printed, how many dollars it should spend on various services. Enabling our corporate customers the ability to identify this information early and then use it in management decision-making is key.

We have a number of customers for whom we develop playbooks for certain kinds of cases, covering the background information on the case; the standard operating procedures for, say, document productions, document review, deposition preparation; the KPIs to report on. The playbook will often include an estimated or expected amount of data and spend. When there's an excess, we flag it for in-house counsel and ensure that it's justified, that it's required to properly handle the case. You can use the portal to display that information for a customer on a self-service basis so they have that information without depending on a monthly report from us.

**MCC:** Law departments are getting more technology-savvy with the help of business intelligence. What more should or can they do?

**Colloff:** I really think that having regular meetings with the various stakeholders and reviewing this information is the only way to make it actionable and usable. Our portal lets you download a dashboard to a Briefing Book (in PDF format) to send to a CFO or CLO, whoever you're dealing with inside a corporation who doesn't want to be involved on a day-to-day basis but whose input we need. Those conversations should be happening on a regular basis – quarterly, biannual or monthly, depending on the company and the portfolio of litigation they're dealing with.

At the end of the day, the fancy charts and the colorful graphs are only helpful if they turn into action for a customer. Our role is to help our customers by providing the tools they need, and walking them through these dashboards to enable better decision-making.

A good example is you've got five cases, and four of those five cases have active users, but only three of those five cases are in active litigation right now. For that fifth case, you're paying for users and hosting that you don't need. You could be in cold storage and have all those users deactivated, and the only reason that hasn't happened is a disconnect somewhere. The dashboard surfaces that information, and the sooner we can surface it on a regular basis, the sooner we can make decisions that save customers money.

**MCC:** Please provide some examples in which clients have used the portal to mine internal data, identify business trends, forecast potential risks for the company or make decisions for the company.

**Colloff:** One of our customers is a large consulting team that provides discovery management services, and they use the portal to aggregate and analyze all of their spend for their customers. They're able to look at historical analysis of their spend per quarter, as opposed to the number of cases they have per quarter, and identify anomalies really quickly. Within

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## **Shamir Colloff**

Chief technology officer at UBIC, Colloff oversees all elements of discovery, including best practices and document review and production.  
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# Big Data Yields Big Results

*Marshal the facts, tell a compelling story, and build a winning case*

**B**usinesses are required to analyze and preserve more and more data as litigation unfolds. Longtime legal technology specialists **Charles Platt** and **Donald W. Myers** are in the trenches with hundreds of millions of data points across multiple systems and networks. Here they explain how big data is reshaping the litigation landscape. Their remarks have been edited for length and style.

**MCC:** Please give our readers a brief overview of your careers in the legal technology space.

**Myers:** I started out as a commercial litigator, where I found myself handling a fair amount of trade-secret work. Around 2004, I realized that the bulk of what we were dealing with in our cases was related to electronic discovery issues, forensic imaging, email, databases and those sorts of things. My practice continued to include a fair amount of time focused on e-discovery, and about four years ago it became my exclusive focus.

**Platt:** I started out in IT, consulting on database development for large corporations and on government contracts. I had been working with a gentleman who eventually went to work doing litigation support, forensics and investigations. He called me up and said, "This is exactly what you would love to do. You need to come join us." So about 14 years ago, I switched over and started working in forensics, litigation support, investigations and expert support. Since then, I have worked on all sorts of different matters, including structured data, cybersecurity incident response and large litigation, all using data forensics and analytics to help understand and explain the facts of the case.

**MCC:** There's a lot of discussion about big data and data analytics in litigation and other areas. Can you tell us briefly what those topics mean to you?

**Platt:** Big data to me is pretty much what it sounds like. It's a lot of information being collected from many sources – Fitbits, iPhones, desktop and laptop computers, tablets and all sorts of devices that we use to stay connected – for huge numbers of individuals. Even our lightbulbs now have Wi-Fi connections and transmit data. Storage is so cheap that we're storing exabytes of information. The trick isn't storing the data, it's the data analytics side. How do we make sense of the information that's relevant to what we want? I've got 100,000,000 records about an individual's transactions, locations, etc. How do I take that data and present it in a way that someone – not a computer, but a person – can review and actually understand it and make decisions based on it?

**Myers:** The amount of information out there is alarming, and it's about things and being kept in ways you would never imagine in your wildest dreams. I'm thinking: How will we get it? How will we analyze it? What can we do with it to help our clients and case teams? Charlie hit the nail on the head. There is just so much information out there in so many devices and networks, and touching on so many other things – computer systems, wireless networks – what can we do to marshal that information and use it in a way that's going to help our case and our clients?

**MCC:** How do you identify what data is available and also relevant to the case at hand?

**Myers:** The first thing we need to do is understand our client's technology. That's true even if it's a case that doesn't involve big data. If we have a case where big data is involved, it's even more important. We've got to get in there to talk with the IT folks. We've got to gain an understanding of where they keep the data, what they use it for, what's involved in accessing it. How long do they hold it? How frequently do they purge, and at what points in time? Once we get our arms around it, we can start to make decisions and determine what potentially could be relevant to the case.

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**Platt:** Communication with the IT staff is critical. It's a human approach. We're talking to people and trying to understand their data. Ideally, we're having an open conversation. The difficulty is that a lot of the time, we can end up talking past each other. For example, we've asked specifically for "email from your email archive" and then had IT come back wondering why nobody ever asked for the backup archive. "Why didn't you tell us there was a backup archive?" "Well, no one asked."

The quality of the conversation is crucial. We're not giving orders or making uninformed demands, we're just having a talk. "What type of email do you have? Where do you keep it? Do you have archives? What kind of archives? Over the past X years, have those archives changed? Has that information been moved? Have you switched service providers?" Asking questions like those is critical.

**Now that so much litigation is moving into big data, to be competent you have to understand the technology.**

– Donald W. Myers

**Myers:** When we're having these conversations, it's important to remember that they're using those systems for one thing – to track financial information or the hours that employees work – and we probably need the information for something different. We've got to make sure that we're speaking the same language, because we're probably asking IT for something that has nothing to do with their typical use of that information.

**Platt:** Little things can make a big difference. "Oh, you wanted *all* the data. I thought you just wanted the data we were preserving specifically for this. We've got other data that goes back another three years." Being clear as to what you're looking for and why goes a long way in getting you where you need to go.

**MCC:** How do you and your teams determine what data needs to be analyzed and what does not? What are the risks associated with these determinations, and how do you mitigate them?

**Myers:** Sometimes it's very easy to figure out what type of data and what types of systems may be relevant to a given case. The challenge – and Charlie and I have dealt with this a lot recently – is when you start learning about systems that, on their face, don't appear to be relevant to your matter. Then you start to learn a little bit more about the systems and you realize they're tracking information that could be highly relevant to the matter at hand. Walking in, you're going to know there are certain systems you definitely need to learn about and that are going to be relevant. But you've got to poke around a bit to understand other systems that may have information that nobody knows about, because it's being used for something completely different and yet could be very helpful.

**Platt:** One other thing that can help is open conversations with opposing counsel. Ask them, "What are we looking for? What are we really trying to get to?" Meet and confer in a spirit of cooperation regarding what data is relevant and what's not. That type of communication is being encouraged more and more, especially when we're talking about risk associated with data. As long as we're being open about what data we have, that can go a long way toward closing some of the risks. The other side is getting a good handle on what data is out there, and if you think it is going to be relevant, you put some type of preservation around it. We can always go back later and analyze it.

**MCC:** How are the courts viewing big data and data analytics? Have you seen changes since the amendments to the federal rules took effect late last year?

**Myers:** I think that the courts' views on big data are very new and untested in a lot of respects. What we've seen in terms of the most recent amendments, even the amendments going back to 2006, is the emphasis in the rules surrounding technology – understanding it, working with your opponents to understand it and cooperate so we're all on the same page and talking about it. If you're not trying to cooperate about big data, nobody wins. I think that's how the rules fit into this. There's too much information and too much time and money that will be wasted if we don't work together.

**Platt:** One trend we've been seeing in matters with big data is that they often never get to the court. We've had a few product liability cases where we've basically come back with data analytics that show a fairly clear picture of no case. From opposing counsel's viewpoint, it's going to cost a lot of time, effort and money, and they're

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## Big Data

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not going to get anywhere because of what the data can show. It's less and less a question of the facts of the matter – we can tell you what the facts are – and more a matter of the merits. We're willing to go to court, but what do they think now that we've shown you what the data says?

**MCC:** *That leads to our next question. Big data is profoundly changing our lives generally. How do you think this will change litigation specifically?*

**Myers:** Charlie keeps saying this, and I'm believing him more and more: As there is more and more data out there, there are going to be fewer and fewer questions of fact, such as whether a car was in a certain place at a certain time. Though I think there will always be some, if there's data around it, you may be able to remove many of those questions completely.

**Platt:** Things we're not even considering today are going to have an impact and increase our ability to put together a compelling story. Even as a technologist, I wonder why I would want my tea kettle to connect to the Internet. Somebody had a reason, and now the world knows when I'm boiling water. These data points start to compound. Maybe my tea kettle alone says it was on at 10 a.m. on the 5th. I could argue that somebody else was in my office at that time. Guess what: All the lights in my office were turned on at the same time. My iPhone says I was in that office. My Fitbit says I just walked up three flights of stairs – and my office is on the third floor. Once you begin compounding all of this data, it starts to tell a very compelling story.

**MCC:** *Do you have any specific examples of using big data successfully in litigation?*

**Platt:** I had mentioned a product liability case where a plaintiff had brought a suit against one of our clients. Their argument was that they were harmed by a product that they purchased at our client's store. They didn't have a receipt, but they did have photographs of the product and several eyewitness affidavits stating that this product was purchased at this store sometime within a specific two- to three-week period. After getting the product and model number from the photos, we went through all of the historical sales records, shipping records and manufacturing purchase orders for products that fit the model number and the product's description. We were able to show fairly clearly that they did not purchase that product from our client's store at the time they said they did. In fact, our client had stopped selling it about a year and a half previously. They did sell a product in the store that month that was similar, and may have appeared to these people to have been the product in question, but it wasn't the product they brought the liability claim on. That data clearly showed that the product in question must have been purchased somewhere else.



*It's less and less a question of the facts of the matter – we can tell you what the facts are – and more a matter of the merits.*

– Charles Platt

**Myers:** One area that gets me is the amount of GPS data that's out there – the ability to tell not where the person was, per se, but where their car was. Then you can take the GPS data and bring in cell-phone information. You can start lining up what tower somebody was at when they were making calls and sending text messages. You can start to tell a pretty good story about what somebody did all day, including where they were.

**MCC:** *Are there any specific rules or concerns about big data and attorney responsibilities? Changes to the ethics rules? Anything we should be aware of?*

**Myers:** Attorneys have always had a duty to provide competent representation. One of the changes we've seen in the ethics rules over the past few years is that some state bar associations have said that in order to be competent, you need to understand technology and how it affects the practice of law. Now that so much litigation is moving into big data, I think to be competent when you represent your client, you have to understand technology, and not just the technology of how our clients are using big data, but how big data can impact a case in our representation of our clients.

**Platt:** As an expert, I think my ethical compass tells me I have a duty to tell you what the data says, and we go from there. I don't hide data. I don't make data up. I present data. I analyze data. I create the ability to view the data in a way that makes sense. I present you with the information, and then it's your decision as an attorney how to use that. I'm not here to manufacture information or do anything other than present to you what the data tells us.

**MCC:** *What are the risks of not being aware of big data and data analytics?*

**Platt:** The biggest risk of not being aware is that opposing counsel is aware. You will either be aware of it ahead of time, or become aware of it too late and find yourself trying to catch up.

**Myers:** The scary part is you might be missing out on an entire aspect of the case. You might be missing out on *the* answer in the case. Charlie mentioned a product liability matter in which big data made that matter go away very quickly because they could prove that they didn't sell that product at that time. You may be passing up an opportunity to help your client and the case.

**Platt:** You can also learn up front that you have a problem – that opposing counsel has a pretty good case. Maybe it's time, before they realize how good a case they have, to start talking.

## A Portal to Action

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those anomalies, they can drill into which services they are overconsuming, vis-à-vis their average consumption historically, and use that to decide where they should either try to negotiate better and limit their production scope or, hypothetically, use a managed services model to up their consumption limits to ensure that they don't have to pay any burst rates.

Here at our company, in fact, we use the Trust portal for our own KPIs and management of our project management organization. We use factors like the number of errors reported as a ratio to the number of milestones managed by a project manager to determine their quality level.

**MCC:** *Relationships between legal and IT can be delicate. Is it time for that to evolve?*

**Colloff:** That's a very culturally sensitive thing at companies. Some legal departments partner well with IT and are able to coordinate their efforts and reporting. For other companies, IT has a lot of functions, and legal is just one of many, and given that functions are often profit centers, and legal is often a cost center, it can definitely be a challenge to get the appropriate attention and partner properly with the IT organization.

Through the portal, we're trying to allow our customers to manage their own destiny in terms of their projects and project management. It also gives them common KPIs they can use in instances when IT partners with legal, to guide decisions in a way that makes the most sense. An example is the amount of data collected versus the number of custodians on a project. After having that metric for a couple of projects in a row, you can turn around and ask your peers in other organizations, "What are you seeing as the average collected data size per custodian?" If yours might be higher, you've got a defensible story to take back to your IT department and say, "Our peers are seeing this number of gigabytes on average. We're seeing three times that amount based on this

portal. We'd like to work with you to limit how we collect data." We're trying to arm clients with information and help them partner in a way that is based on empirical data, instead of just giving it lip service.

**MCC:** *What is the most important priority for leaders and technology experts in corporate law departments as they adopt new legal technology solutions to manage their data?*

**Colloff:** The people running legal in corporate organizations really should be thinking about controlling their own information governance process and understanding what's happening with their data. That's as simple as ensuring that they're using the appropriate sort of security questionnaires and vetting processes when they select external vendors and law firms, or as complex as tools like we've been talking about, like the portal.

There's a tendency to outsource complex challenges, to say, "I've got a big, nasty problem. I'll get a vendor to deal with that." In some cases, "vendor" is just another word for "scapegoat." With corporations more and more responsible from the court's perspective, it's important that the corporations are more empowered to be that responsible party. If you outsource without managing the process, you can end up in a heap of trouble.

Our differentiator is that this portal is a fully customizable solution. Business intelligence isn't a new idea, but it's starting to get some traction. Some people say, "I have BI. I have this one dashboard that gives metrics about the files people are tagging." Yes, that is BI, and it is helpful, but in a very limited capacity. The reason I think that the Trust portal is a universal solution is that it's not just a recipe for giving everyone what they want. In other words, the solution is purpose-built. The way we're set up is to provide each individual customer with a dashboard that meets their specific needs and answers their specific questions. Now, that's intelligent business.



# Cash Register Receipts: The Newest Prop 65 Violator

*The latest culprit of Proposition 65 violations includes everyday items like receipts*

By Meredith Jones-McKeown / Sheppard Mullin & Chris Mackay / AMEC Foster Wheeler

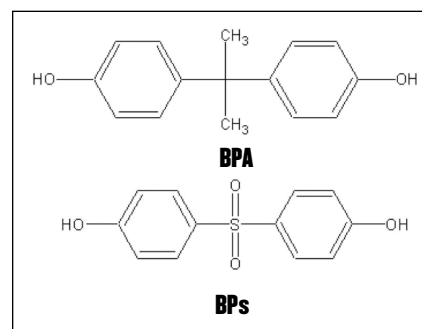
**B**usinesses operating in California have long been aware the perils of utilizing any of the almost 1,000 chemicals identified by the state of California as potentially causing cancer or reproductive harm under California's Proposition 65. Consumer-facing businesses have learned to identify high-risk Prop 65 targets: soft, flexible plastics; faux and colored leathers; and any kind of brass or metal that may contain lead or other heavy metals. If they miss, scores of Prop 65 "bounty hunters" are waiting in the wings to seek penalties and attorney fees from businesses when they are caught including these chemicals in their products without a compliant warning label.

But since California typically leads the way on consumer regulations, even businesses that don't operate in California should be aware of a recent addition to the Prop 65 list: bisphenol A, or BPA. Consumer advocates have long voiced concerns about the use of BPA in baby bottles, as a liner for canned goods, and in other plastics and products. And as of May 11, 2016, BPA has been added to the Prop 65 list, so many businesses are scrambling to eradicate its use from these known sources. But one source may come as a surprise: BPA may be lurking in your cash register receipts and other thermal papers.

## BPA Added to the Prop 65 List

Effective May 11, 2016, the California Office of Environmental Health Hazard Assessment added BPA to the list of Proposition 65 chemicals known to the state of California to cause reproductive harm. BPA commonly exists in certain plastics (particularly polycarbonates and epoxys) and UV-cured inks, as well as in the liner for canned foods. But many do not realize that thermal paper (commonly used in printing machines such as cash registers, credit card machines ATMs and automated ticket printers due to the fact that it does not require ink stock) is also likely to contain BPA –

**Figure 1: Chemical structure of bisphenol A (top) and the related bisphenol S (bottom).**



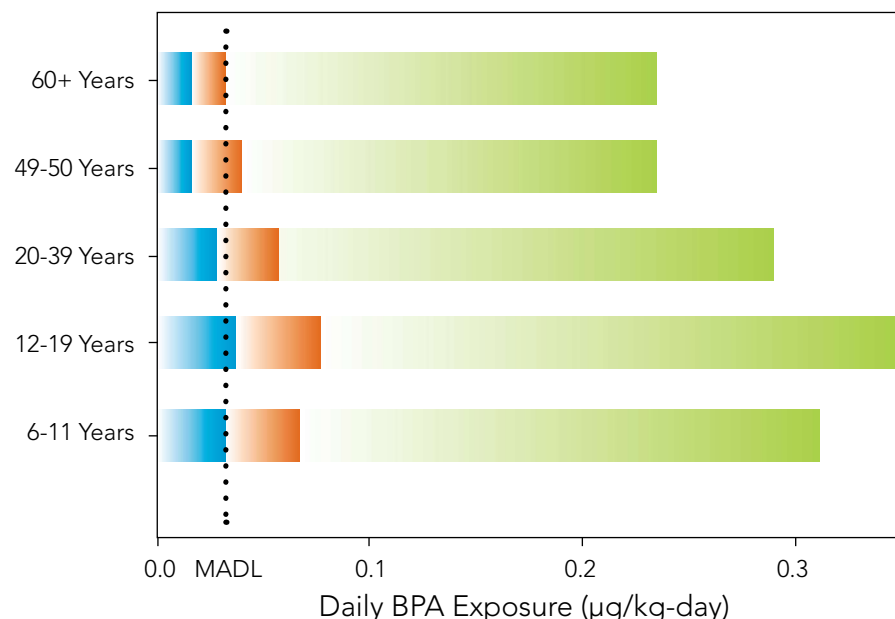
BPA (figure 1) is a common chemical used in the adhesives and plastic industries. It is the common monomer in epoxy adhesives (the resin component) and is also used as a monomer high-impact polycarbonates used to make reusable bottles, safety glasses and CD/DVDs. Other advanced plastics such as polyether and polyether ether ketones as well as polysulfonates may contain BPA. BPA may also be found in PVC and vinyl (softened PVC), where it is sometimes included in the product as both a polymerization terminator and as an antioxidant.

and businesses that fail to phase out the use of BPA-containing thermal paper before May 11 will eventually run the risk of receiving a Proposition 65 Notice of Violation from the plaintiffs' bar. Under Prop 65, businesses have a one-year grace period after the chemical has been listed to achieve compliance.

## BPA and Thermal Paper Technology

The technology of thermal-sensitive paper is straightforward. Normal paper is coated with an ink in a form that has little color at neutral or high pH, but becomes vivid at low pHs. Common inks include the leuco inks that demonstrate this pH-dependent color change. The paper is then sequentially coated with a thin layer of a temperature-sensitive polymer and a solid state acid, which acts as a developer. When the paper is heated by the printer head, the polymer melts and the dye and acid

**Figure 2: Daily BPA exposure based on urinary metabolite excretion by age.**



The 2003 to 2004 National Health and Nutrition Examination Survey performed annually by the Centers for Disease Control and Prevention measured BPA metabolites in participants and back-calculated exposures by age group. The results are illustrated in figure 2. Almost all of this exposure is through inadvertent ingestion. Bars represent the 25<sup>th</sup> (blue), 50<sup>th</sup> (red) and 95<sup>th</sup> (green) percentile estimates from the 2003 to 2004 NHANES survey. The vertical dashed line represents OEHHHA's proposed dermal MADL/kg-day.

combine, the pH of the ink drops, and ink shifts to the colored form. When the paper cools back to room temperature, the thermal polymer condenses over the visible ink, thereby preserving the writing.

In order to function correctly, the acid component of the thermal dye must be solid with moderate water solubility, chemically stable within a large range of temperatures, and possess a low vapor pressure. BPA is one of the few chemicals that meet these criteria, and it provides the additional benefit of being low cost.

## Why BPA Is on the Prop 65 List

The toxicology of BPA is complex, and its effects on humans are unknown. BPA has been classified as

a weak estrogenic mimic, meaning that it produces effects similar to the female sex hormone estrogen. Binding studies with BPA and the classical estrogen receptors suggest its activity to be 1,000 to 10,000 times less than estrogen. However, some animal studies show impacts at lower concentrations, and some researchers have opined that BPA may act as a selective estrogen receptor modulator, while other researchers have advanced alternative theories.

The OEHHHA has suggested (but has not yet confirmed) a maximum allowable daily limit, or MADL, for BPA of 3 µg/day through dermal exposure. This is extremely conservative and may not be supported by data. Current animal study data suggests that a more appropriate MADL would be on the order of 150-250 µg/day.<sup>1</sup>

## Dermal Uptake Concerns

If OEHHHA enacts 3 µg/day as the daily dermal limit as currently proposed, there will be an urgent need to remove all BPA-containing thermal paper from the market. The reasons are twofold. First, since exposure to the receipt is automatic for every customer who receives a receipt, traditional



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*Continued on following page*

# Assigning Value Is More Than a Number

*Proper valuations for S corporations and limited-liability companies have critical consequences*

**By Eric J. Barr / Marks Paneth LLP**

**D**etermining the proper value of an ownership interest in a business is often a critical component of an attorney's legal representation in connection with a marital dissolution, a business split-up, estate and gift planning, employee stock ownership plan (ESOP) transactions, mergers and acquisition advisement, and others. Even though experts are generally engaged to provide an estimate of such values, attorneys should have a certain level of knowledge that will increase the odds of a successful representation in the event that the valuation is contested.

Approximately 80 percent of the businesses filing U.S. federal income tax returns are S corporations, partnerships or limited-liability companies, collectively known as pass-through entities (PTEs). Valuing PTEs is one of the oldest, least resolved and, some would say, most poorly defined issues challenging the business valuation profession. Here are the crucial matters that attorneys need to know about valuing PTEs:

## **To Tax Effect or Not?**

Appraisers are still challenged by the tax effect issue. This may be the most important valuation issue that appraisers and attorneys must address on a contested matter. For example, if one appraiser tax effects the subject company's income stream at a rate of 40 percent and the other appraiser does not tax effect it, the resulting conclusions of value will likely

be very different. Know the foundational reasoning for your expert's opinion, as well as the opposing expert's opinion. Understand whether the model (if one is used) has been peer-reviewed and, if so, by whom.

## **No "One Rate Fits All"**

Certain appraisers take pride in being able to testify that regardless of the case facts, the venue, or whether they are the plaintiff's, the defendant's or a neutrally appointed expert, they always use a particular rate when tax effecting the earnings of a PTE. This makes no sense because (a) the level of earnings impact a company's effective income tax rate, (b) federal income tax rates change, (c) federal tax rates with respect to dividend income change and (d) different states have different tax laws.

## **PTEs Have Different Values**

Understand the difference between S corporations and limited-liability companies. S corporations have restrictions as to the types of entities that can be shareholders, as well as the number of shareholders. The members of limited-liability companies, assuming that they are actively involved in the operations of the business, are subject to self-employment taxes on the earnings that pass through (unlike shareholders of S corporations, who are not subject to self-employment taxes on pass-through earnings). State law may also provide certain restrictions for one type of entity (i.e., restricted partnerships and restricted limited-liability companies

under Nevada law) but not another. The buyer's tax consequences when purchasing the equity of an S corporation are markedly different than the tax consequences of buying the equity of a partnership or LLC. These factors, among others, impact value.

## **Know the Case Law**

It seems that there is an endless stream of cases involving the valuation of PTEs. Some cases pertain to the fair *value* standard of value; others deal with the fair *market* standard of value. Knowing that these cases exist, the theory underlying the decisions, the venue, the standard of value, the relevant fact patterns, the tax rates in effect as of the valuation date, etc., are critical to knowing whether or not your appraiser can rely on a particular decision.

## **Tax Rates Change**

And they will continue to change. If the process of valuation involves determining the risk-adjusted present value of future net cash flows, why apply current tax rates to an income stream that will be subject to known and knowable changes in tax rates? Challenge all inappropriate tax rate assumptions.

## **Income Retained Impacts Value**

An owner of a PTE is subject to the proportionate share of taxable income of the PTE whether or not

such earnings are distributed. Accordingly, two companies that have identical earnings and cash flows can have materially different values if one company distributes all of its earnings and the other one does not make distributions.

## **Forensics Are Important**

If data that has not been subjected to an appropriate forensic analysis is used as inputs for the valuation, such data may not accurately reflect the true economic activity of the business being valued. When discovery is limited, an appraiser's forensic analysis may be unreliable, and the old adage about "garbage in, garbage out" may apply.

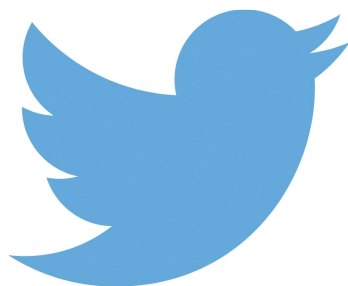
## **Always, Always, Always**

Ask for authoritative support from your experts. Make sure that your expert can support each and every valuation assertion contained in the report. Finally, use your experts to assist in cross-examination and to identify contradictions between authoritative, published positions and those taken by the opposing expert.



**Eric J. Barr**  
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## **Prop 65**

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Proposition 65 warning systems may not be sufficient to avoid liability for alleged exposures. Second, because BPA in thermal paper is present in its monomer form, some studies have suggested that it is more available for transfer to people than BPA constituents of polymers, with one study suggesting that a single five-second contact by two fingers resulted in the average transfer of 1.2 µg of BPA (~0.22 µg/cm).<sup>[2]</sup> The study also indicated the transfer amount would increase about 15 times if the fingers were moistened. Interestingly, multiple exposures did not increase the BPA concentration on the skin, nor did longer holding periods (60 seconds compared with 5 seconds). This breaks

down to an exposure of 3 µg/day (0.05 µg/kg-day) for the incidental user (i.e. consumer) and about 15.8 µg/day (0.24 µg/kg-day) for the occupational user (e.g. sales clerk).

## **Alternative Materials**

BPA is not the only possible acid that can be used in thermal paper. Substitute materials include sulfonyleureas or substituted salicylic acids, such as zinc di-tert-butylsalicylate. Another alternative commonly used in thermal paper is bisphenol S; however, because BPS itself has been implicated as a potential endocrine disruptor, it too may face limitations in the near future.

*To review the footnotes to this article, visit <http://www.metrocorpocounsel.com>*





## Special Section

# LIFE SCIENCES

### In This Section:

Crafting IP for Medical Devices  
**Stephen Schaefer / Fish & Richardson**

Participation, Collaboration, Quality  
**Debra M. Perry & Elizabeth K. Monahan / McCarter & English, LLP**

"Clear Evidence" Preemption Success  
**Emily Pincow / Weil, Gotshal & Manges LLP**

Post-Grant Review Roils Patent Litigation Waters  
**Manish K. Mehta / Sheppard Mullin Richter & Hampton LLP**

## MCC INTERVIEW: John Pennett / EisnerAmper LLP

# Balancing Revenue Against Risk

*Education and zero tolerance for deficiencies are key*

**John Pennett's** Life Sciences practice at **EisnerAmper** ranges from fledgling companies in incubators to global pharmaceuticals, but his insights here on implementing compliance controls, assessing reputational risk and vetting third-party vendors are widely applicable. His remarks have been edited for length and style.

**MCC:** Can you share some of your experience and background with our readers?

**Pennett:** I have headed our Life Sciences practice for the 12 years I have been at EisnerAmper and for about 10 years at my firm prior to that. My experience includes helping entrepreneurial companies think about ways to finance and grow their business, to develop their products, and to put systems in place to achieve those goals.

The clients I serve range in size from very early-stage incubating companies through venture and private equity backed companies, and into public companies. I just finished my two-year tour as co-chair of the Center for Commercialization of Innovative Technologies, an incubator located in New Brunswick, New Jersey. I serve as an advisor and mentor at eLabs, which is a New York City-based virtual incubator, and as a content provider/mentor/panelist at several other incubators in New York, New Jersey, California and Pennsylvania. Those are fun groups to work with, and helping younger companies is always exciting.

**MCC:** Your life sciences practice covers many aspects of compliance and regulatory advice. What's a sampling of best practices for life sciences companies when they are dealing with the U.S. government?

**Pennett:** Some companies separate their business into two distinct units – one that sells to the government and one that does not – believing this is a more effective way to isolate the commercial activities from the governmental activities. There is a point of view that considers the practice not as transparent as it could be, though setting up sister companies along those lines is becoming an increasingly popular mechanism.

Certainly regardless of whether that happens, good communication and active educational programs are required to make people aware of what pricing rules require in terms of the impact on sales to the government and the company's certification process. Pharmaceutical companies have been under a lot of scrutiny, so education and zero tolerance toward deficiencies with corporate rules and regulations is very common.

### John Pennett

Partner-in-charge of the Life Sciences and Technology groups at EisnerAmper.  
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**MCC:** When selling to the U.S. government, what compliance issues do companies face with relation to the pricing rules and certification you just mentioned?



**Increasing profits versus the reputation risk of increasing prices is a very delicate balance.**

**Pennett:** There are a pretty complex series of rules regarding pricing when selling to the government, and it generally revolves around the concept of the "average sales price." The government mandates that its programs get your best price, and the company, typically the CFO, provides a certification of its pricing guidelines on a periodic basis. This certification involves crunching a lot of data – and a thorough understanding of the government pricing rules and definitions.

There is, and should be, a lot of attention paid to the compliance activities around the government pricing criteria. A company can get into trouble, for example, if a salesperson offers a discount to one client and somehow the government is paying a higher price than that. In certain circumstances, the price certifications are then inaccurate, and the government is entitled to a refund.

A lot of mistakes occur that are not necessarily fraudulent in intent, just the happenstance of deals that maybe didn't make it through all the channels for approval. It

requires a lot of diligence, attention and education so that both the sales and operational personnel, as well as accounting, know what is going on and they are properly reporting their prices and filling out their certifications.

**MCC:** To take a broader view for a moment, how does pricing work generally within pharma and life sciences companies? What is your perspective on the ethics of pricing?

**Pennett:** There are little, if any, regulations that would not allow companies to increase their prices. They are still commercial ventures, and they still have those rights. In some cases, there are obviously contracts that they need to comply with, but at the expiration, they can change the price.

The dilemma that executives face – and now it has become more acute to the board of directors too – is weighing the commercial goal of increasing pricing and increasing profits, therefore improving returns to the stakeholders, versus the reputational risk of increasing prices by more than what is perceived to be an acceptable level. Some companies have been very successful at turning underperforming products into well-performing economic products, but that reputation risk requires careful thought. It's a very, very delicate balance.

Obviously the current testimony in Congress will be going on for a while, but I don't know that any changes in the rules and regulations will necessarily come out of it. Certainly drug pricing and the overall healthcare costs throughout the entire chain are going to continue to be under a large degree of scrutiny. Legislators have an easy target in the perceived deep-pocket pharmaceutical companies.

**MCC:** Where do shareholder rights end, if ever?

**Pennett:** You could make an argument that it is the company's responsibility to its shareholders to try to maximize the return on the assets that they own. If the markets

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## Balancing Revenue Against Risk

Continued from previous page

will allow a price increase, supply and demand would mandate that they have to think about that. In certain global markets, legislative bodies determine pricing of product – the company just has to decide if it wants to participate in that market.

The other side of that coin is that you are either dealing with governmental payers, private insurers or in some cases even private payers, and they are bearing the cost increase. So where is that line between what is reasonable in terms of economics versus the perception of being too aggressive in the pricing models?

**MCC:** So then how can companies use profit sharing or royalty deals to increase their revenue?

**Pennett:** A lot of companies do use profit or revenue sharing arrangements to drive more product activity through their books. There has been an increasingly large quantity of quasi-virtual pharmaceutical companies – often good marketers that don't have the physical capabilities to manufacture the products themselves – that partner with other groups that either own the technology or are manufacturing the product. This way they take advantage of their own skill set in marketing, say, to drive product revenues for the group as a whole, and for them in particular.

Some very creative deals have been done that make the economics work for both sides in terms of how those profits and royalties are shared, as a way to bridge the economic gap between commercialization risk, technology and approval risk, and ultimately what the competitive risk may look like. These risk-sharing deals often are designed to help cash flow considerations for one or more of the parties as well.

**MCC:** Many life sciences companies work with offshore vendors for clinical trials, manufacturing and other services. How can they minimize the risks in those relationships?

**Pennett:** The risk that you have to manage whenever you are dealing with any outsourced vendor, but in particular an offshore vendor, is strict adherence to quality measures and compliance with rules and regulations. As an example, some Indian generic pharmaceutical manufacturers have been in the news far too frequently for compliance aspects with respect to Food and Drug Administration regulations on manufacturing facilities.

With any outsourced facility, especially one that is not so easy to visit on regular basis, having a really strong sense of comfort that the vendor is totally embracing the quality aspects and requirements is critical. That is applicable both in the clinical work as well as the manufacturing and distribution side of the business. The industry has had too many black eyes to accept any degree of noncompliance, so you need to be really careful that you are building into your processes the mechanisms to review, audit and monitor the quality of the work that your partner is doing throughout the process.

**MCC:** What indicators should corporate in-house lawyers look for in terms of risks with offshore vendors?

**Pennett:** Luckily, with respect to the FDA and the other regulatory agencies, there is a lot of information in the public domain. You can see from a diligence perspective how a company has fared historically in its compliance activities. A significant amount of diligence with respect to quality procedures is critical, and that includes talking to their customers and other vendors associated with them to get a sense of comfort that the vendor you are looking at has both the right policies and procedures and the right mind-set toward compliance.

**MCC:** It appears that in recent years there has been a break between regulatory advisors and compliance teams. Can you talk a little bit about how their roles and responsibilities differ?

**Pennett:** The compliance teams have been more along the lines of your traditional internal auditors, so they are checking that people comply with the particular rules in place. More of that is now being driven by systems and technology, so certain aspects, like Sunshine Act reporting, that used to be manually intensive are now done through technology.

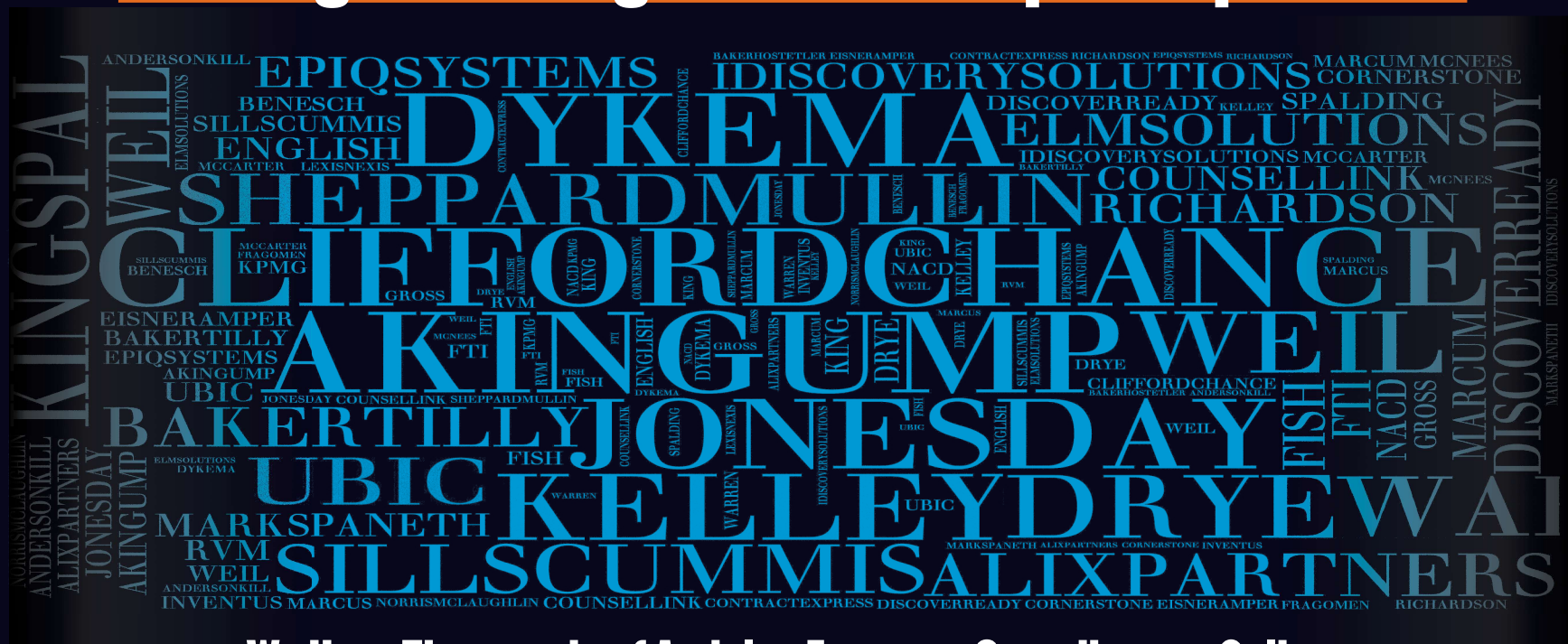
The regulatory advisors are focusing more on the processes and building those best practices into the company's operation. These are educational aspects: They are building the culture around compliance, around conformity, so you see more chief compliance officers, chief ethics officers and positions like that being developed. Those jobs are being given a much higher degree of visibility within organizations, especially within the pharmaceutical industry. A lot of companies are putting attention in that area because of the negative press about the industry as a whole.

**MCC:** Let's talk about the internal controls, specifically for life sciences companies. What do they look like?

**Pennett:** A lot of pharmaceutical controls are based around information technology and the volume of data received from vendors and customers. With third-party logistics companies, wholesalers and manufacturers, an awful lot of data is gathered throughout the supply chain and the sales life cycle. Most companies use technology in a very significant way to keep track of these large volumes of transactions, analyze the data, check for contract compliance and proper classifications, and group and analyze it.

One of the really important areas for pharmaceutical companies is to make sure that they have excellent internal control policies and procedures around their IT environment, especially surrounding third-party data. Making sure that data is coming into your organization, going through the IT systems, and being stored, secured and backed up properly is critical to the organization. Further, pharmaceutical companies are acutely aware of the need to meet any threat of cybersecurity attacks – especially with respect to the volumes of personalized information maintained. Cybersecurity is an area of great concern for chief information officers, executives at pharmaceutical companies and boards of directors.

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### MCC INTERVIEW: Stephen Schaefer / Fish & Richardson

# Crafting IP for Medical Devices

*Targeted patent strategies can help companies gain a competitive advantage*

**Stephen Schaefer** of **Fish & Richardson** discusses emerging trends in patenting medical devices, the challenges and opportunities ahead at the Patent Trial and Appeal Board, or PTAB, and how a shifting patent landscape has affected the medical device industry. His remarks have been edited for length and style.

**MCC:** Tell our readers about your patent practice and your experience representing clients in the medical device arena.

**Schaefer:** The biggest part of my practice is helping medical device companies, particularly early stage companies, protect and position their technologies to gain competitive advantage. I learn my clients' business at a very deep level so the intellectual property (IP) strategy can support their business in a very direct way. This includes creating patent protection barriers and defensive strategies. I have a strong background in patent litigation and an in-depth understanding of judges and juries, who may someday be the audience determining the fate of the patents that we are creating. This background helps me develop patent strategies for clients that will hold up under the rigors of litigation if necessary.

Contested post-grant validity proceedings in the Patent Office are another large and growing part of my practice. I have served as lead counsel in over 30 inter partes review (IPR) matters on medical device patents over the course of the last three years alone.

**MCC:** What competitive issues do medical device companies typically encounter, and how can a good patent strategy minimize those risks?

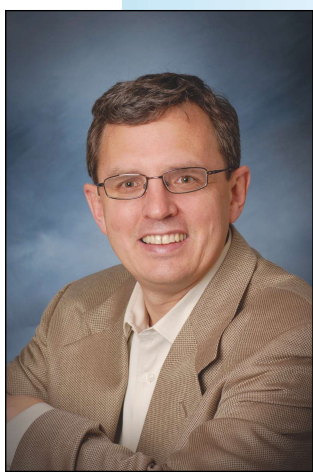
**Schaefer:** Competitor patent litigation is commonplace in the medical device area, even more so than in many other industries. That means that every company operating in this space, including early stage medical device companies, must have a solid defensive strategy which requires a deep understanding of freedom to operate risks and good judgment about the severity of those risks. Indeed, investors and acquirers pay a lot of attention to freedom to operate issues during due diligence.

It's important that these risk assessments be done wisely from a budget standpoint, so the client has the remaining budget to pursue its own patent filings. As with many things, a balanced approach is best. I'm not afraid to tell my clients not to waste their budget or time on defensive studies and positioning when that won't strengthen their overall IP position. For example, it is possible that a company may be spending too much time and money on freedom to operate and risk mitigation, and doing so might be taking away from the strength of its own patent filings.

I advocate following an 80-20 rule on freedom to operate studies, focusing on identifying and assessing the higher risk issues, but it takes judgment and experience to recognize where to draw that fine line. It's important to remember what can, and even more importantly what cannot, be gained through a freedom to operate study effort. The client can often get value from a freedom to operate effort when it leads to risk-reducing design changes at an early stage, before making design changes becomes too difficult from a regulatory standpoint. However, a client won't get the assurance of not being sued, even on patents that are identified and where a reasonable invalidity position is developed.

I often hear freedom to operate study efforts can mitigate risks by leading to an early license of patents that may be a problem down the road. In reality though, it is very infrequent that a freedom to operate effort has led to in-licensing a patent. It is also difficult in most cases to identify "stretch" patents with a disclosure that does not look like the device a client is developing but which has been prosecuted to obtain claims that cover the client's device. It is unrealistic in my view – and extremely costly – to aspire to identifying these often hard-to-identify patents in a freedom to operate effort, and most often the cost-benefit assessment does not justify the additional resources.

**MCC:** You have done countless IP due diligence studies and advised many large companies and venture funds regarding their investments in medical device companies. Tell us about that.



**Schaefer:** I have worked with some of the leading venture capital funds focused on the medical device space, which has exposed me to a wide range of medical device products and business plans. What I love most about IP due diligence projects is seeing how entrepreneurs see the world, and how they see solutions where others don't even see problems.

I approach every IP due diligence project by starting with an understanding of the value proposition for the target company from a clinical and business perspective. I review the investor deck in detail and discuss with the client what it is that makes the client excited about the investment. In the end, I view my job as assessing how the IP supports the value proposition. While a positive IP assessment makes it easier to make an investing decision about a target company, a negative assessment doesn't necessarily mean the deal is dead. For example, I once evaluated a target company for a client and found its patent filings to be lacking, being focused on mechanical details instead of the new and compelling clinical therapy. There was no patent filing that described the medical therapy from beginning to end or its benefits. The patent strategy was clearly misdirected, because previous patent counsel lacked experience in the medical device arena and didn't understand what would stand up to an obviousness challenge in court or in the Patent Office. Despite the negative IP assessment, I also considered remedial actions as part of

the diligence. In the end, our client made the investment because the clinical therapy was so compelling and there was still time to fix the IP. After the investment, I then worked with the company and its patent counsel to formulate new patent filings that protected the value proposition for the company.

**MCC:** Why is developing a client's patent strategy vis-à-vis competitors so important?

**Schaefer:** The most important building block of a strong patent position is developing an understanding of the patent landscape relevant to the client's business goals. This is critical to making strong early patent filings, knowing what to focus on and not wasting resources in the process, and in understanding freedom to operate risk issues. Understanding the patent landscape and its relevance to the client's business objectives ultimately becomes a living, growing component of the IP effort during a company's growth process.

**MCC:** Fish is regularly named a top law firm at the PTAB. How are you using IPRs in your patent and litigation strategies for medical device companies?

**Schaefer:** Every single medical device litigation involves an IPR strategy whether or not IPR actions are actually filed. That's because the PTAB has not been shy about invalidating patent claims in IPR proceedings for obviousness. In fact, for those IPR proceedings that go all the way to a final written decision by the PTAB, and don't settle before that decision is handed down, only 14 percent of patents emerge unscathed with all challenged claims being confirmed. A daunting 72 percent emerge with all claims invalidated. For medical device cases, the statistics are comparable, and the number of IPR filings directed to medical device patents is growing.

Some of my medical device clients were early adopters of the IPR option, and we have had great success in invalidating competitor patents that put hundreds of millions of dollars of my client's product at risk. And although it's much more difficult to achieve, we've also seen success in withstanding a PTAB validity challenge.

Bottom line, the IPR option has changed the litigation game. And it has opened some eyes on the patenting side. You can't cut corners and think you're going to have enforceable patents.

#### Stephen Schaefer

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*Continued on page 32*

# Participation, Collaboration, Quality

*The CDRH engages to advance its updated strategic priorities*

**By Debra M. Perry & Elizabeth K. Monahan / McCarter & English, LLP**

**B**uilding on the FDA's goals and strategies for creating a national evaluation system for medical devices, the FDA has recently increased its focus on collaboration with the medical device community, as well as patient involvement, to promote public health with high-quality and safe medical devices.

The FDA recently released "2016–2017 Strategic Priorities"<sup>1</sup> for the Center for Devices and Radiological Health (CDRH), which explains how the CDRH intends to accomplish these goals. The CDRH has implemented new programs and strategies that focus on patients' input, stakeholder engagement and data transparency. According to "Strategic Priorities," the CDRH's current vision is to "assure the U.S. is the world's leader in medical device regulatory science, innovation, and manufacturing; establish a robust post market surveillance system; assure that devices on the market remain safe, effective, and high quality; and assure consumers, patients, caregivers, and providers have access to the information they need to make well-informed decisions."

## **Patient Participation**

One CDRH focus is on partnering with patients to provide patient perspective regarding patient preference information, risk-benefit analysis and device labeling. The CDRH has used patient representatives for advisory opinions, but it recently increased patient-reported outcome measures in clinical studies to meet patients' needs. Last year, the CDRH established the Patient Engagement Advisory Committee to communicate regarding important topics that require patient input, and CDRH intends to identify and define the regulatory uses of patient report outcome measures, both premarket and postmarket, to identify

patterns and gaps. This committee consists of outside experts who will conduct public meetings twice yearly and is intended to provide additional perspective on patient preference, risk-benefit analysis and labeling of devices. Patients will be able to submit adverse event reports and other methods of outcome reporting to provide additional input on device regulation, with an expectation that this will avoid problems posed by inadequate patient communication, which has sometimes led to medical complications. Because patient groups are often sponsored by the medical device industry, patient advocates have concerns and question whether segregating patients' representatives into their own panel is helpful.

The CDRH believes the key to success is the use of real-world data to support the efficient identification of safety issues with medical devices. More patient involvement through informed decision-making will be important, as will increasing how information is presented to make it more patient-friendly. The patient perspective will be used to analyze risks and benefits, which the CDRH expects will better meet the needs of patients and promote the safety of medical devices. One example of this effort is the development of the Patient-Centered Benefit-Risk Framework and the assessment methods catalog developed through participation in the Medical Device Innovation Consortium (MDIC). The MDIC, a public-private partnership with the FDA and other stakeholders, aims to advance regulatory science in the industry by developing tools and methods to manage the total product life cycle of a medical device through the use of maturity models. There is currently no recognized quality system maturity model, and the goal of the MDIC is to understand various models to create a plan for developing a model for industry partners and regulators in the medical device community to use.

*In partnering with the industry, the FDA creates a public-private alliance that fosters a safer system.*

## **Industry Collaboration**

The CDRH has also prioritized establishment of a planning board to collaborate more regularly and efficiently with the medical device community. The CDRH first set out a strategy and steps for creating this type of national system in 2012 and 2013, and multi-stakeholder groups in 2015 endorsed the vision, upon which the CDRH now intends to build its main goals in this area. The CDRH intends to increase both access to and use of real-world evidence to support regulatory decision-making. The CDRH's goal is access to 25 million electronic patient records with device identification by the end of 2016 and access to 100 million such records a year later.

The FDA's National Medical Device Evaluation System Planning Board proposed a public-private partnership "coordinating center" to create a national system to evaluate medical devices, made up of members of the pharmaceutical industry, government, industry groups and researchers. The goal is for the coordinating center to encourage quality healthcare and reduce costs. The FDA intends to accomplish that goal by allowing manufacturers to receive approval for their devices more quickly, utilizing data use agreements that allow members to share data, such as electronic records and clinical trial data. The National Evaluation System uses real-world data to efficiently identify and manage device safety issues. This system would encourage innovators to study their technologies

and bring their products to patients in the United States first. This priority demonstrates the focus on patients and stakeholders, particularly as it relates to reporting, to advance patient safety and meet patient needs.

## **Case for Quality**

The third main focus of the CDRH is to achieve quality and organizational excellence through implementation and expansion of the Quality Management Framework. The CDRH worked with the FDA Office of Regulatory Affairs in 2011 to create the Case for Quality initiative, which is defined in "Strategic Priorities" as:

an initiative undertaken in collaboration with other members of the device ecosystem, to identify those practices that can promote a culture of quality and the implementation of a quality management approach that fosters continuous product quality. CDRH envisions a future state where the medical device ecosystem is inherently focused on device features and manufacturing practices that have the greatest impact on product quality and patient safety. Internally, this requires a shift in our traditional regulatory approach, toward a model that is preventive of problems before they occur, that adapts to changes in science and technology, and that rapidly addresses events that impact safety. Externally, this requires partnerships and shared responsibility among FDA, industry, practitioners, and patients to continually evaluate and adjust based on experiences across the full life cycle of a device.

The core components of the Case for Quality include a focus on quality, enhanced transparency of data and increased stakeholder engagement. Specifically, "Strategic Priorities" explains, "The [Case for Quality] initiative treats compliance as a baseline, giving greater emphasis to the FDA and stakeholders focusing on critical-to-quality practices that correlate to higher quality outcomes. The FDA is working with stakeholders to promote manufacturers' implementation of critical-to-quality practices in day-to-day device design and production. The FDA is also looking for ways to recognize these practices in its own operations."

Further, the FDA plans to enhance data transparency by leveraging the broad array of data it receives from recall



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# Another Successful “Clear Evidence” Preemption Defense

**By Emily Pincow / Weil, Gotshal & Manges LLP**

**T**his month, the District Court of Utah issued a preemption decision addressing the “clear evidence” standard set forth in the Supreme Court’s decision in *Wyeth v. Levine*. This is yet another critical decision for drug manufacturers relying on a preemption defense to failure to warn claims.

In *Cerveney et al. v. Aventis, Inc.*, the plaintiff was prescribed Clomid, which is a selective-estrogen-receptor modulator used to induce ovulation in women who are unable to ovulate. Following her second round of the drug, the plaintiff discovered that she was pregnant and subsequently gave birth to a son, who suffered from birth defects. The plaintiff contended that these birth defects were the result of Clomid remaining present in her body during conception. She claimed that the use of the drug prior to pregnancy can cause several birth defects and cited numerous studies in support of her theory. The plaintiff argued that Aventis had a duty to warn her prescribing physician that the drug could cause birth defects if taken prior to pregnancy and that had she been aware of the hazards, she would not have purchased or taken the drug.

Since 1976, Clomid’s labeling has consistently warned about the risk to a fetus if Clomid is ingested during pregnancy. However, the FDA has never required that the label warn about birth defects if ingested prior to pregnancy. In 2007, Terence Mix submitted a citizen petition to the FDA, requesting that the FDA do a number of things, including order changes to the labeling and a package insert for Clomid and its generics to include warnings of the drug’s ability to cause birth defects if ingested prior to conception. Mix supplemented his petition to the FDA five times to include scientific literature that he claimed supported his requests. In 2009, the FDA denied Mix’s Citizen Petition. In September 2009, Mix filed a

Petition for Reconsideration, asking the FDA to reconsider changing the labeling of Clomid to include warnings suggesting an association with preconception use and birth defects. With it, he included more scientific data. In March 2012, the FDA denied Mix’s Petition for Reconsideration. Clomid’s current label, which was approved in October 2012, does not contain warnings suggesting an association between Clomid use prior to pregnancy and birth defects.

Aventis moved for summary judgment, arguing that the plaintiff’s failure to warn claims were preempted. Specifically, the drug company argued that the FDA would not have permitted Aventis to include the warnings suggested by the plaintiff, thus the plaintiff’s state tort law claims were conflict preempted because it would be impossible for Aventis to comply with both state and federal law.

In addressing Aventis’ defense, the court explained the “clear evidence” standard announced by the Supreme Court in *Wyeth v. Levine*, 555 U.S. 555 (2008). There, the Supreme Court stated that “absent clear evidence that the FDA would not have approved a change to [the drug’s] label[,]” the Court would “not conclude that it was impossible for Wyeth to comply with both federal and state requirements.” *Id.* at 571. Although the Supreme Court’s decision did not define “clear evidence,” a number of courts have applied the “clear evidence” standard in *Levine*.

Aventis argued two sources of evidence that proved that the FDA would not have approved a stronger warning label on Clomid prior to 1992. First, the company argued that the FDA’s rejection of Mix’s Citizen Petitions in 2009 and 2012 were clear evidence that the FDA would not have approved a warning on

Clomid’s label suggesting an association between use prior to pregnancy and birth defects. Second, Aventis claimed that the FDA’s history of approving the drug labeling that includes statements contrary to the plaintiff’s theories was further support that the FDA does not associate Clomid use prior to

*The FDA’s response to citizen petitions is indicative of a rejected labeling change if a petition post-dates the alleged injury.*

pregnancy with birth defects. The court agreed with Aventis on both of these grounds.

First, the court explained that several courts have concluded that citizen petition responses are indicative of whether the

FDA would reject a proposed warning labeling change where a citizen petition *post-dates* the alleged injury and addresses the failure to warn claim proffered by plaintiff. Specifically, the court relied on the Southern District of California’s preemption decision issued last year in *In re Incretin-Based Therapies Products Liability Litigation*, 2015 WL 6912689 (S.D. Cal. Nov. 9, 2015). The court found that in this case, the FDA heard and rejected the plaintiff’s theory in Mix’s Citizen Petitions, which post-dated the plaintiff’s Clomid use by over 15 years. The

court emphasized that Mix’s Citizen Petitions argued the plaintiff’s exact theories to the FDA, and the FDA specifically rejected them. Thus, the court held that the FDA’s denial of the plaintiff’s theories embodied in Mix’s Citizen Petitions constituted “clear evidence” that the FDA would not have permitted Aventis to strengthen Clomid’s label.

Despite concluding that the “clear evidence” standard was satisfied, the court went on to address Aventis’ second argument regarding the FDA’s inaction. The court also found it dispositive that the FDA, in addition to rejecting Mix’s Citizen Petitions, has consistently approved Clomid labeling that includes affirmative rejections of the plaintiff’s theories. The court found that the FDA’s inaction, coupled with its comprehensive review of any association between Clomid ingestion prior to pregnancy and birth defects, to be highly persuasive evidence that the FDA would not permit Aventis to strengthen Clomid’s labeling as the plaintiff requested.



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# Post-Grant Review Roils Patent Litigation Waters

*More changes to come as Congress, the courts and the Patent Office weigh in*

*The America Invents Act (AIA) has had a profound impact on patent litigation, particularly surrounding inter partes and other post-grant proceedings. Below, Manish K. Mehta, who handles patent litigation across an array of key sectors, including pharmaceuticals, discusses both the defensive and offensive strategies that companies can employ in the rapidly evolving patent arena. His remarks have been edited for length and style.*

**MCC:** *As an IP litigator you represent companies ranging across sectors, from life sciences to manufacturing. Are the changes to the patent laws, particularly the introduction of inter partes review proceedings, having different impacts on different sectors?*

**Mehta:** Absolutely. I have been involved in litigation spanning the pharmaceutical, medical device and heavy machinery industries where we have filed or considered filing IPRs. In my experience, the number of competitor IPRs in the pharmaceutical sector is lower than in other industries. I think that is because many pharmaceutical disputes are litigated under the Hatch-Waxman Act, which covers the regulatory approval process for generic versions of a branded drug and provides the statutory requirements that need to be considered in assessing whether to file an IPR. For a company looking to make a generic version of a branded product, it must certify to each of the patents listed in the Orange Book (which is not actually orange or a book; it's on the FDA website). A generic company or Abbreviated New Drug Application (ANDA) filer can submit a Paragraph IV certification that the proposed generic product does not infringe the Orange Book patent(s) or that the Orange Book patent(s) is invalid. This is commonly referred to as a P-IV certification.

Once the innovators or NDA applicants receive a P-IV certification, they have a 45-day window to file a lawsuit to secure a 30-month stay of the final approval process for the generic product. P-IV certifications happen quite frequently because the Hatch-Waxman Act incentivizes generic companies to challenge Orange Book patents by granting them a 180-day "first filer" exclusivity, which goes to the first generic or generics to submit a P-IV challenge to a particular product. That means some generic companies may have limited market exclusivity for 180 days, which can be very valuable. However, this exclusivity can be forfeited under certain circumstances. Since the IPR process moves very quickly and a petition can be filed prior to a lawsuit by the patentee, there may be a final decision from the federal circuit prior to the expiration of the 30-month stay, which could trigger the forfeiture of the 180-day exclusivity. The law in this area is still evolving. However, there is this regulatory framework to be careful about when considering an IPR petition in a Paragraph IV litigation. It's not to say that it hasn't been done, but it is definitely something to be mindful of.

Moreover, because Hatch-Waxman litigation frequently involves multiple generic filers, some defendants may not have an incentive to file an IPR petition if they have a unique non-infringement position. They might not want to challenge the patent via the IPR proceeding because that may open the floodgate for all other generics to enter the market around the same time. If a non-infringement position, which hopefully is unique to me, could get me on the market before everyone else, why would I want to challenge the validity of the patent?

**MCC:** *Has your strategy changed for patent litigation defense? What approaches are most likely to lead to a successful outcome, especially given the sensitivity of in-house counsel to what are perceived as out-of-control IP litigation costs?*

**Mehta:** The strategy now is very different. In my opinion, whether to file an IPR petition is a mandatory consideration when mounting a patent infringement defense. In my practice, our strategic defense planning includes quickly evaluating whether to file an IPR or some other type of post-grant proceeding. Time is of the essence here because there is a limited window to file an IPR petition if you've been sued on that same patent – the one-year time bar. If you don't file an IPR petition of a patent within a year of being served with a complaint alleging infringement on that patent, you're going to be time-barred from doing so.

The ability to challenge a patent in a more favorable forum is a major shift in the patent litigation defense landscape. For in-house counsel, one primary concern is cost surrounding the substantial work needed to assess filing an IPR petition. You want to find a way to get the work done properly but not blow the in-house litigation budget. In most cases, we use a multistep process. We identify the relevant claims that may be asserted against our accused product. Sometimes it's worthwhile to focus your IPR petition on only the claims that matter as long as you have strong non-infringement defenses with respect to the rest of the claims. Next, we assess the strength of our non-infringement defenses. If they're strong enough to withstand an infringement allegation based on non-infringement – stronger, say, than your invalidity defense – we may not want to file an IPR petition. The burden of proving infringement is on the patentee, and you'd rather put the onus on the patentee in district court litigation if you're confident that you have a strong non-infringement position.

If it's not as strong as you'd like, then you may want to evaluate the strength of the invalidity defense. I tend to do these two steps in parallel with invalidity because you may have equally strong non-infringement and invalidity defenses. You may still want to launch the invalidity attack in the IPR proceeding because of the challenger-friendly aspects of an IPR proceeding: lower burden to prove invalidity, broader claim construction and no presumption of validity. If you use the invalidity defense, you have to remember that it's based on prior art patents and printed publications only. If your defense is based on prior use or sale, you can't raise it in an IPR proceeding. You may need to take the nature of your invalidity defense into account in deciding on whether or not to file an IPR. Lastly, I would look at other defenses, such as failure to claim statutory subject matter under 35 U.S.C.101. This defense has become more popular in light of the *Alice* decision. You may be able to get the case dismissed via a dispositive motion under Rule 12(b)(6) and circumvent the expensive cost of litigation through trial.

As in-house counsel attempt to control costs, I'd recommend asking counsel for a phased approach, assuming the company is not looking to settle based on a nuisance value. In conducting the filing due diligence up front, one option from a business perspective is to ask your outside counsel to execute each of these phases under a "not to exceed" fee cap so you have some cost certainty. Nine times out of 10, this due diligence will be useful even if you don't file an IPR petition.

**MCC:** *Where is the action these days as far as patent litigation goes? Is it pharma or medical devices?*

**Mehta:** Both of those are very litigious sectors. Looking at the pharmaceutical space, according to a study by Lex Machina there were 466 ANDA litigations filed in 2015, up from 434 the prior year. That's a significant number of patent cases and a result of multiple companies seeking to make a generic version of the same branded product. This results in multiple lawsuits involving the same drug. For example, I was recently involved in a pharma case where there were more than seven related litigations over the same drug.

Looking at the medical device industry, while it's less litigious in terms of volume, there are still a sizable number of competitor cases, and some of the largest patent verdicts over the last couple years are in this space. One example is *Stryker v. Zimmer*, in which Zimmer was ordered to pay more than \$200 million for willful infringement. The federal circuit reversed the willfulness finding, which slashed the damages award, and now the issue concerning the scope of enhanced damages is before the U.S. Supreme Court and being closely watched by the patent community. While the number of cases in the medical device space is definitely lower, they are very meaningful.

**MCC:** *Some litigators say they are seeing a new type of litigation spawned by the America Invents Act – patent trolls challenging branded pharma patents to move a stock price. Have you seen any of this?*

**Mehta:** I'm not directly involved, but I've been watching this trend closely. It's unclear to me whether they are trading on the stock prices or what the net effect is, but one can make that assumption based on the handful of non-practicing entities filing IPR petitions on Orange Book patents that cover drug products. It's an interesting tactic with significant upside to the petitioner. Non-practicing entities can do this because they do not need standing to file an IPR petition. Anyone can challenge a patent regardless of whether they have a competitive product or not. There has been a movement to create a standing requirement that could potentially curtail or limit these types of challenges, including proposed legislation.

I don't think a standing requirement will be put into place. It would undermine the

## Manish K. Mehta

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purpose of IPR proceedings, which was to seek review of patents that may not be patentable or susceptible to challenge because they are not novel or they're obvious in light of the prior art. It would be difficult to draw fair lines of demarcation between which parties are eligible to file an IPR proceeding and which are not. From a practical standpoint, I don't see how we can strike a fair balance.

**MCC:** *What's this issue concerning real parties-in-interest in the IPR context? It seems to be a requirement that is rather benign, but there has been some activity on this front.*

**Mehta:** There are rules in place that require the petitioner to identify all of the real parties-in-interest (RPI) in the petition. There is no bright-line test to determine who is a RPI, but the Patent Trial and Appeal Board (PTAB) has provided guidance. An RPI is a party or parties at whose behest a petition was filed. Typically, an entity is an RPI if it funds, directs or controls the IPR proceeding, or if it could have exercised control over a party's participation in a proceeding.

The RPI requirement in the petition is an important tool to prevent other interested entities from challenging the same patent on the same or similar grounds as long as those folks were related to the original petitioner or were a RPI to the original petitioner. Why is that? In a final written decision in IPRs there is an estoppel provision that bars RPIs from asserting claims the petitioner raised or reasonably could have raised during the inter partes review in litigation. This prevents serial filing. That's why it's important to have all of the RPIs identified in the petition, and the Patent Office and the PTAB have taken this requirement very seriously. There can be serious ramifications if it's later discovered that all of the RPIs were not identified. For example, the board can vacate the original filing date of the petition, which means the petitioners must file a subsequent petition that identifies all of the RPIs and the filing date will be the date of that second petition, which can implicate the one-year time bar if there is a parallel litigation on the same patent. If the new filing date is one year after the date of service of the complaint that alleges infringing of that patent, the petitioner won't be able to file an IPR proceeding on that patent.

**MCC:** *From a litigator's perspective, what are the tricks to building a bulletproof patent portfolio?*

**Mehta:** I have a few strategies. One is maintaining a pending application related to your core technology. It's absolutely critical because it can help mitigate any harm to your patent portfolio if any of the issued patents are subsequently challenged in an IPR proceeding. It might even give you an opportunity to strengthen your portfolio through what you learn from any ongoing proceeding on a related patent, and it can help you craft claims to overcome any invalidity arguments that were made during those proceedings. It also allows the patent owner to strengthen claims in the related application that can withstand subsequent IPR challenges if the application issues.

The other benefit, and we do this quite frequently, is an opportunity to draft claims that cover the petitioner's technology because you now know that they clearly are interested in your core technology. It shouldn't be very difficult to figure out what they are doing commercially based on publicly available information and to build a set of claims that cover it to provide you with a stronger infringement position.

On the petitioner side – I represent both patent owners and petitioners – one of the first things we do is look at the patent family of any patent that we are looking to challenge in assessing whether to file an IPR petition. The presence of a pending application related to the patent that we're looking to challenge is one relevant factor in assessing whether to file an IPR petition.

The second tactic that I discuss with my clients is creating dependent claims with value, meaning that the dependent claims of any patent application that you draft should include meaningful limitations. In studying patents that are potential IPR candidates, I often see that the dependent claims include meaningless or obvious limitations and do not add additional nuggets of novelty to the invention. This makes it much easier from a petitioner's perspective to invalidate those claims. You also need to build in a series of dependent claims in your claim sets to require the petitioner to link multiple prior references together. This is one of the areas where much can be done to help withstand IPR challenges from a patentee's perspective.

And, finally, bolster your portfolio with design patents, which are a smart and



## Evaluating whether to file an IPR petition is a mandatory consideration when mounting a patent defense.

inexpensive way to strengthen your patent portfolio. Design patents are also eligible for IPR proceedings, but there haven't been many challenges to date. One of the benefits of an IPR proceeding for utility patents is that the threshold is lower to demonstrate invalidity. For design patents, it's virtually the same standard as in district court litigation, which inures to the benefit of the patentee. It is also rare to invalidate a design patent based on obviousness grounds. I would definitely recommend including design patents in your portfolio.

**MCC:** *Are there times that it makes sense for companies that are usually on the defensive side on patent litigation to go on the offense? When is an offensive strategy appropriate?*

**Mehta:** There are times when companies should be proactive. One strategy is to challenge a patent or patents owned by a third party that may have a profound impact on your business. For example, there may not be a lawsuit or threat of litigation just yet, but if company A identifies patents owned by a third party that potentially could be problematic for company A's business, that may be a circumstance where you would want to consider looking at an IPR petition to remove the uncertainty that can cloud the business. Instead of taking a wait-and-see approach, you may want to be proactive by removing this risk to your business. And I would make the challenge robust. First, consider challenging all of the patent claims, not just the ones you think you might infringe, because you will eliminate the possibility of a non-challenged claim being asserted in litigation. Also, one of the true benefits of an IPR proceeding is to promote business resolutions by advancing settlement discussions. Essentially, by attacking all of the claims, you're calling into question the entirety of the patent, not just a subset of claims. That can create significant leverage.

I also recommend preparing an IPR petition and providing it to the patent owner prior to filing, and then potentially negotiating an amicable solution. Why is this important? Once you file an IPR petition, you can't unring the bell. The petition will be public and will remain in the public domain even if the parties reach a settlement and the PTAB grants a request to terminate the petition or proceeding. The IPR petition, if done properly, provides a road map to potential invalidity arguments that could be easily incorporated by another party in a subsequent IPR. The patent owner should see value in the non-disclosure, which will give the challenger leverage in negotiating a settlement. And you can always file the petition if the negotiations fall through without the concern of a time bar if there is no parallel litigation.

**MCC:** *Now that we have some experience with post-grant proceedings, where do you see things moving in the months and years ahead?*

**Mehta:** We are going to see a lot of changes coming from three areas: court decisions, the legislature and the Patent Office itself. We can expect the federal circuit to weigh in on the PTAB decisions. We've already been seeing this happen recently. One hotbed is the scope of the estoppel provision that we talked about earlier, where the RPIs, if there is a final decision, will be estopped from raising those grounds that they did or could have raised in the IPR proceeding. In a case decided on March 23, 2016, in *Shaw Industries Group v. Automated Creel Systems*, the federal circuit held that grounds that were not instituted by the PTAB on the basis of redundancy will not be subject to estoppel in later proceedings. As you can see here, the federal circuit is now starting to carve out exceptions to the broad, and what can be seen as overbearing, estoppel provision that was originally enacted in the IPR proceedings.

The Supreme Court is also going to start looking at some of these issues. They've granted review of *Cuozzo Speed Technologies v. Lee*, which was the first IPR decision ever by PTAB, and will consider two issues: the claim construction standard used in IPR proceedings and whether a PTAB decision to institute a trial can be reviewed after the final written decision. These two points will have a profound impact on future proceedings. Oral arguments were held on April 25, 2016, and we are patiently waiting the Court's decision.

Lawmakers are seeking to address such things as the standing issue – which parties can file an IPR petition – and also create a presumption of validity of a patent just like in district court, and then employ a claim standard consistent with the *Phillips* decision.

In terms of the statistics, the IPR was seen as pro-challenger or anti-patentee at its inception, but I think we're starting to see the pendulum begin to swing back in favor of

*Continued on following page*

and adverse event reports, in addition to inspection results, to support device quality in numerous ways. For example, the CDRH has stated in “Strategic Priorities” that “to enhance independent analyses by stakeholders, the FDA is exploring publishing our data so that it can be automatically accessed and searched by external analytical tools. We’re also conducting analyses of our data and publishing these analyses. These reports will draw from our recall data as well as inspectional observations and warning letters.” Lastly, the FDA has been meeting with stakeholders to obtain feedback on the Case for Quality, which encourages a collaborative approach to compliance and quality control in the area of medical devices, and promotes new initiatives that differ from more traditional oversight models.

Additionally, the Voluntary Compliance Improvement Program and the Medical Device Single Audit Program (MDSAP) will complement the Case for Quality by identifying issues of quality and factors that will create new ways for patients to have access to the best medical devices possible, even when financial barriers exist. The program will coordinate manufacturing facility inspections across five coun-

tries by using certified inspectors from private firms. To date, the industry has not embraced this program. Only 45 manufacturing sites have expressed interest in participating, far short of the goal of 330 sites becoming involved by the end of 2016. The FDA has signaled that participation is voluntary, but it could become mandatory to reduce the number of inspections by having a single regulatory audit. The CDRH plans to have systems and procedures in place by September 30, 2017, to be eligible for ISO 9001 certification, and it intends to use resources to continue building upon the CDRH Quality Management Framework.

The CDRH has outlined goals for promoting this type of collaborative culture, including strengthening both the FDA’s culture of quality within the CDRH and product and manufacturing quality within the larger medical device ecosystem. The FDA and the CDRH believe that the Case for Quality does more than simply allow for improved oversight of manufacturers and increased collaboration and sharing of ideas. It also allows the FDA to collaborate with stakeholders to identify and share important quality practices. The FDA expects that manufacturers’ bottom lines will benefit from the Case for Quality, and it has cited a study that found that these types of practices can reduce

quality-related costs by up to 20 to 30 percent and can increase profits by 3 to 4 percent. In sum, the goal is that the Case for Quality will create higher-quality devices that encourage the goals of the FDA by protecting and promoting the public health. This would enable the FDA to identify quality-capable firms to which less compliance attention and resources must be directed, which will in turn promote production of high-quality devices.

### What Can the Industry Expect?

Increased inclusion of patients and stakeholders in the discussion of medical devices and their safety is the key to success, according to CDRH, and partnering with the medical device community to create a public-private partnership is expected to foster a better and safer system. As stated in “Strategic Priorities,” the CDRH is prioritizing its collaboration with members of the medical device community pursuant to the Case for Quality “to identify, develop and pilot metrics, successful practices, standards, and evaluation tools that will be specific to the medical device industry and focus on assuring product and manufacturing quality.”

The CDRH’s recent efforts to engage with patients and stakeholders will become even more important per the new “Strategic Priorities,” and as

counsel to medical device manufacturers, we will monitor how these goals and strategies fare. Many stakeholders have sought the use of more FDA resources and effort on postmarket vigilance, and for more efficient approvals as a result, which could result in shorter approval times for certain devices. Some consumer advocates and health researchers have been critical, opining that the FDA should use scientific research – not patient preference – to decide whether to approve medical devices. Some agree that patients should have a voice, but they remain unconvinced that having them on their own panel will offer real benefit. They also remain skeptical about whether the patient representatives of the patient-centric advisory committees are independent and without experience in devices.

Notwithstanding the paucity of manufacturers participating in the audit program, manufacturers should expect audits will model the scope declared in their applications for certification of services, as well as on the regulatory requirements of countries where the manufacturer sells or registers its devices. To prepare, manufacturers should perform internal audits using applicable MDSAP documents.

To review the footnotes to this article, visit <http://www.metrocorp.counsel.com>

### Post-Grant Review

Continued from previous page

patent owners, which should bring a sigh of relief from innovative companies that are seeking to patent their innovations.

The IPR institution rate has dropped from around 75 percent in 2014 to 68 percent in 2015 and is hovering around the same mark this year. But the institution rates don’t tell the entire story. Once the petition has been instituted, the rate at which the claims have been canceled or held to be unpatentable remains very high – around 80 percent. This tells patent owners that the battleground should

be focused on preventing the institution of an IPR proceeding, and the patent owner should spend a considerable amount of time and resources filing a preliminary patent owner statement and fighting the institution of the petition instead of being coy and waiting to mount its full defense post-institution.

Those are some areas where I think we’re going to see a lot of change. It’s an exciting time, and I’m glad to have clients that are active in this space and to be able to continue to represent them in these types of proceedings.

### IP for Medical Devices

Continued from page 27

**MCC: Patent licensing is a critical component of many medical device companies’ strategic initiatives. What are the hot issues driving patent licensing right now?**

**Schaefer:** The issues I’ve most often encountered recently have to do with field licenses and issues of what parties are required to be involved in a lawsuit in order for one licensee to bring the lawsuit. The law here has been evolving and, I think, is not well understood by the attorneys typically drafting license agreements. Recent case law makes it very important for a field licensee to ensure that other field licensees to the patent are obligated to participate in a patent enforcement action.

**MCC: What is on the horizon in terms of recent rule changes, litigation or PTAB cases affecting medical device companies?**

**Schaefer:** I’m watching closely the U.S. Supreme Court’s case in *Cuozzo Speed Technologies*, which involves the important question of how claim construction is conducted in inter partes review proceedings. In my opinion, the Patent Office’s application of the “broadest reasonable construction” in post-grant proceedings significantly undermines the efficiency goals behind the America Invents Act, but my hunch is that the Supreme Court will defer to the Patent Office’s rule-mak-

ing authority and uphold the use of that claim construction standard.

**MCC: You work with both large medical device companies and startups. What are the similarities and differences in the IP issues you tackle for each?**

**Schaefer:** What I do for large versus small medical device companies is often very different. For a smaller company, I am typically accountable for developing the IP strategy and overseeing all of the patent related tasks. My larger clients have very talented in-house legal counsel who do much of that work, so I support them with advice on best practices and strategic initiatives. But in the end, both large and small companies want the same thing – experienced guidance to reach their IP and business goals.

**MCC: Looking at the global market, what do you see as the major IP opportunities and threats for medical device companies?**

**Schaefer:** The biggest thing I see on the global stage in terms of opportunities is Europe’s new unitary patent system. The system may go into effect as early as 2017. It changes the existing country-by-country enforcement scheme to one enforcement action, covering all 26 EU countries, and thus has the possibility of greatly increasing the competitive leverage afforded European patent rights.

Forward-looking information designed to help corporate law departments manage more efficiently and keep in the know about new technologies and innovations



# FOCUS: OFFSHORE FINANCIAL CENTERS

## MCC INTERVIEW: Kelli Moll / Akin Gump Strauss Hauer & Feld LLP

# Hedge Fund Scrutiny Continues

*Heightened attention is driving up costs and increasing transparency*

*As the hedge fund industry has matured, regulation of funds has intensified, particularly since the global financial crisis beginning in 2008. Kelli Moll, who has been working with fund clients for more than 20 years, provides her perspective on where things stand regarding regulation and enforcement of hedge funds, and where they might be headed. Her remarks have been edited for length and style.*

**MCC:** *The hedge fund industry has experienced tremendous change since the financial crisis of 2008. You've written about some of the fallout, such as the evolving demands of investors and regulators. What are the main changes, and what impact are they having on the industry and on your role as an advisor to the industry?*

**Moll:** The main changes since the financial crisis are threefold: changes in the registration requirements for investment advisors, requiring most advisors who were previously exempt from SEC registration to register; changes in the European landscape for marketing investment funds; and changes in the inspection and enforcement environment. The additional regulation has resulted in increased transparency and reporting to the regulators, including the filing of Form PF and Annex 4 in Europe, and, in general, has increased the cost of compliance.

This has had the largest impact on the emerging market manager, where additional compliance has created new barriers to entry. For all investment managers, compliance is now a larger component of their internal infrastructure than pre-crisis. The biggest current impact on the industry, however, has been in the inspection and enforcement arena, where the SEC has taken a more aggressive regulatory posture. Enforcement in the industry has increased generally and, more noteworthy, even in situations where corrective action was being undertaken. The SEC has used its enforcement powers to call out large institutional managers for prior practices and are imposing fines related to those past practices. Furthermore, during routine examinations, the threat of enforcement has resulted in restitution for alleged violations.

**MCC:** *Fund governance has been under continuing scrutiny from regulators, particularly in Washington and London. What's the state of governance and director duties, and where do you see things going, particularly in the wake of the Weaving decision out of the Cayman courts?*

**Moll:** Fund governance is another area that has evolved significantly since the global financial crisis. With European managers, independent directors are more the norm, and the governance role historically has been more robust than with U.S. managers. Post-crisis, and in particular post-*Weaving*, the decision from the Cayman courts, we see most managers employing professional independent directors, and many of them using split boards, which is using different independent directors from different service providers to enhance their governance process.

Many managers have moved either to semiannual or quarterly board meetings, with special meetings being called if there are interim issues that the board needs to address. Boards are much more actively involved in various aspects of fund governance, including reviewing and approving side letters, bank account and custodial account opening procedures; analyzing and improving actions to address various conflicts of interest; and looking at any waivers of fund terms.

**MCC:** *The International Consortium of Investigative Journalists has roiled the offshore waters, which could have an impact on asset managers. Is this more of a political/public relations issue, or is it having real legal/business impacts on your clients? Is it changing the equation for evaluating competing offshore and onshore jurisdictions?*

### Kelli Moll

*A partner with Akin Gump, Moll focuses her practice on formation and ongoing operation of hedge funds and private equity funds, as well as counseling investment advisors.*  
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**For all investment managers, compliance is now a larger component of their internal infrastructure than pre-crisis.**

**Moll:** Currently, we have not seen much legal fallout from the Panama Papers scandal, although this is a relatively recent development, as news just hit the U.S. markets. I do think that, for investors connected to the scandal, there's going to be an ongoing political and public relations issue. Furthermore, for offshore jurisdictions, there will be continued public pressure to provide more transparency.

Cayman, British Virgin Islands and Bermuda are the most used jurisdictions by U.S. managers in connection with establishing offshore funds, and all of these jurisdictions have moved toward greater tax transparency and OECD – Organization for Economic

Co-operation and Development – cooperation. We're not expecting a lot of impact on those jurisdictions.

**MCC:** *The AIFMD, or Alternative Investment Fund Managers Directive, has imposed specific disclosure requirements for certain fund managers, and the SEC is looking at compliance across a number of areas. There's also been a push from many corners, including the OECD, for greater tax transparency. The G-8 has gotten into the act, and anti-money-laundering laws are a continuing concern. How do you see fund regulation evolving? What is causing the most concern for your clients?*

**Moll:** Form PF, which is required under U.S. law for private fund managers, and Annex 4, which is required under AIFMD, have resulted in significant information being provided to regulators regarding the private fund industry. That includes disclosures on the types of investors, assets under management, types of investments, use of leverage and derivatives, and geographical focus, among other data points. It remains to be seen what additional substantive regulation of the kinds of investments private funds may make may result from the information being provided as regulators look to assess the impact the hedge fund industry has on the trading markets as a whole.

In addition, there are three tax reporting regimes now in place that are affecting the private fund industry: one from the U.S. (FACTA); one from the UK; and one that covers the rest of the world, which is called the Common Reporting Standard. I hope, at some point, that the UK will fold into the Common Reporting Standard to limit the number of tax compliance regimes, but that still remains to be seen.

On the anti-money-laundering front, we're expecting rules to be adopted for the industry in the U.S., which will, in large part, codify a process that has already been established by our clients. It's hard to predict how other regulations will evolve, but what we are likely to see is continued enforcement focus on better disclosure and mitigation of conflicts of interest.

**MCC:** *You've been involved with fund formation and management for a wide range of fund clients over the years. How has the landscape changed over the course of your career?*

**Moll:** There's been a great evolution in the hedge fund industry, which reflects its maturation. Institutional investor interest has grown exponentially during my more than 20 years practicing in this space, which has affected terms and the level of investor negotiation. The industry swings back and forth now from being a sellers' market or a buyers' market, and current market terms reflect the balance of power between managers and investors. Furthermore, regulation has had a profound effect on the internal infrastructure of clients and the need for larger middle- and back-office operations. In addition, new service providers continue to enter the industry to provide a variety of solutions, whether it's compliance, IT and cloud solutions, cybersecurity analysis or AIFMD platforms.

# Stepping Up Offshore Governance

*Director duties move to the fore in Cayman and other offshore centers*

Some of the most hotly contested issues around corporate governance and operations have arisen from the Cayman Islands. **Hayden Isbister** and **Simon Dickson** of **Mourant Ozannes** summarize the firm's offshore practice, litigation trends and the increased need for – and use of – corporate secretarial services. Their remarks have been edited for length and style.

**MCC:** Please tell our readers about your firm and your offshore practice.

**Isbister:** We are one of the leading global offshore law firms, advising on the laws of the British Virgin Islands, the Cayman Islands, Guernsey and Jersey. We have a substantial presence in each of those jurisdictions, as well as offices in Hong Kong and London. In addition, our corporate services affiliate, Mourant Ozannes Corporate Services (MOCS), provides corporate services to financial institutions, global corporates, managers and various sovereign wealth funds. In terms of our clients, they include many of the world's leading financial institutions, public companies, corporations and fund promoters, as well as high net worth private individuals.

Within the umbrella of the Cayman Corporate group, we advise on all aspects of corporate and commercial work, investment funds (both hedge and private equity), and banking and finance. We also have the largest litigation practice in Cayman, as well as an international trusts and private client practice. We handle many installments of restructuring work that is often affiliated and led by our litigation practice.

Before moving to Cayman, I worked in the corporate and commercial department of Minter Ellison, a top-tier law firm in Australia. I have been in Cayman for almost nine years, and I continue to focus on corporate work, with an emphasis on investment funds, including hedge funds, private equity funds, hybrid funds and all other variations of funds. I also enjoy working on banking and finance transactions, which are often linked to an investment fund structure.

**Dickson:** As Hayden says, we have the fastest growing and most successful litigation practice in the Cayman Islands. We also have successful litigation practices in the British Virgin Islands, Hong Kong and the Channel Islands. The Cayman Islands litigation department has a particular focus on insolvency and restructuring, associated fund litigation, and fraud and asset tracing. We have a growing regulatory and contentious trust practices too.

In the insolvency space, the department is probably best known for the Primeo liquidation (arising out of Madoff) and the associated litigation against the SIPA trustee Irving Picard, HSBC and the Herald fund, and the *Weaving* liquidation and associated litigation. In the restructuring space, we are probably most recognized for our work on Arcapita bank. In the fraud and asset tracing practice, our headline case is the *Algozaibi v. Saad* fraud, where we act for the plaintiff, with claims of over \$6 billion.

**MCC:** Hedge fund governance has been under continuing scrutiny from regulators, particularly in Washington, D.C., and London. What's the state of governance and director duties, and where do you see things going, particularly in the light of the *Weaving* decision out of the Cayman courts?

**Isbister:** *Weaving* brought directors' duties into the spotlight, particularly in the Cayman context of investment funds. Whilst *Weaving* was a significant decision, it did not tell us anything new in relation to the duties that a director must uphold when acting as a director of a Cayman corporate fund. It did, however, make us recognize that we do not want directors of Cayman funds behaving in the manner of the directors related to *Weaving*.

Since *Weaving*, the Cayman Islands Monetary Authority (CIMA), the regulatory authority of open-ended investment funds in the Cayman Islands, issued a statement of guidance on matters of fund governance (SOG). This has been a welcome addition to the Cayman funds industry. Apart from setting out good practices of supervision and the monitoring of service providers that a fund's board must do, one of the main requirements is that the board must meet a minimum of twice per year for all regulated funds. Many boards were already adopting this practice (or more), but now it has brought more consistency across the industry.

**Weaving didn't tell us anything new about director duties, but it brought governance to the forefront of the industry.**

– Hayden Isbister



Our firm has seen a significant increase in requests through our corporate services affiliate, MOCS, for board support or corporate secretarial services. This is designed to ensure that the board meetings are conducted in a professional way in terms of preparing the board packs with all of the necessary information, organizing the meetings and then having proper minutes of the meetings prepared. Clients have appreciated having us offer board support services as it makes the whole governance process quite smooth.

In addition to the SOG, we now have a Directors Registration and Licensing Law (DRLL), which requires directors of CIMA-regulated funds and investment management companies registered as "excluded persons" under the Securities Investment Business Law to be either registered or licensed (as the case may be) before they can be appointed to the board of a relevant covered entity. CIMA conducts this process through its website portal.

As a result of the SOG and DRLL, we have seen the state of governance improve. A number of former attorneys, accountants, administrators and various other industry professionals have become independent directors. This rise in new independent directors is driving an increase in split boards – boards that include two independent directors, with each director represented from a different independent director services firm. All of these changes have improved the state of governance, which remains an important consideration for institutional investors, as well as smaller investors who are investing in Cayman funds.

While the SOG and DRLL were both a direct result of *Weaving*, it is worth noting that Cayman has always been quick to react whenever there are issues of concern, such as those issues identified in *Weaving*. As a result, Cayman remains

*Continued on page 36*

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# Momentous Changes to Federal Rules of Civil Procedure Have Taken Effect

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# Perspectives on Procedure: A Civil Rules Roundtable

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### Civil Justice IDEAS, INITIATIVES

#### Perspectives on A Civil Rules

**Relief from ESI Over-Preservation**

**Carmen G. McLean / Jones Day**

S... [Text continues]

**Low Profile, High Impact**

**Karin Scholz Jensen / BakerHostetler**

**Proportionality: Old Wine, New Bottles**

**Anthony M. Candido & Sarah A. Salkowsky**

The real problem: Tech Dan Regard / iDiscovery Solutions

# PERSPECTIVES ON PROCEDURE

In a special edition of Civil Justice Playbook, Metropolitan Corporate Counsel presents a mosaic of opinion on the landmark revisions to the Federal Rules of Civil Procedure that took effect on December 1. Our "Civil Rules Roundtable" features a dozen thought leaders weighing in on the main event, Proportionality, but also on some less-heralded but no less momentous nooks and crannies, where the known knowns, the known unknowns and the unknown unknowns of the changes lurk. Rules junkies will also want to check out our interviews with discovery gurus Daniel L. Regard of iDiscovery Solutions and Phil Richards of DiscoverReady who bring their deep expertise and tech-centric insights to MCC.

### Civil Rules Roundtable Most and Practicable Items

[Text continues]

### Procedure: A Civil Rules Roundtable Portion - Not Perfection

**Rozie Windfelder / McCarter & English LLP**

[Text continues]

### Civil Rules Roundtable

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an accepted and recognized offshore investment funds jurisdiction that has a flexible investment funds regime set within a clear and effective regulatory environment, which is implemented by CIMA. There are also other appealing features, such as the number of quality and experienced legal, administrative and accounting services providers, and the ease of registration procedures.

**MCC:** *What types of litigation are most common, and are you seeing an increase in enforcement actions?*

**Dickson:** We continue to see a broad array of fund litigation, ranging from shareholder disputes to full-scale litigation against service providers. On the insolvency side, although there have been fewer winding up petitions over the last year, we continue to see an uptick in the number of insolvency related matters coming from Asia. For example, we have recently been heavily involved in parallel applications in Hong Kong and the Cayman Islands in respect of an application to wind up a multibillion dollar operation.

In the restructuring space, there remains a significant interest in the use of light touch provisional liquidators to facilitate onshore restructuring, particularly with respect to Chapter 11 proceedings. We successfully used this procedure in the Arcapita matter, where the court allowed a moratorium over claims against a Cayman subsidiary in Chapter 11 proceedings together with the appointment of provisional liquidators with limited powers to oversee the progress of the US restructuring. The appointment allowed the Chapter 11 proceedings to move forward and ultimately allowed us to facilitate a reorganization of the Cayman subsidiary in the US. This model has been used a number of times since and is growing in popularity.

In the fraud market, there remains a steady flow of instructions. To date, no fraud case being litigated in Cayman rivals the *Saad* litigation, which is due to go to trial in July.

We are seeing more regular use of the statutory mechanisms for the taking of depositions and the obtaining of evidence to assist in onshore fraud litigation. Whilst these statutory steps can be time-consuming, they remain an excellent and underused tool for discovery from offshore centers.

We have seen a great deal of interest in applications under Part XVI of the Cayman Islands Companies Law where, in the context of a statutory merger, a dissenting shareholder can trigger the court process for determining "fair value" of its shares. The recent decision of the court in *Integra* gave useful guidance as to how the court will approach such applications, and it approved in large part the approach taken by the Delaware and Canadian courts.

On the regulatory side, the increasing burdens are causing financial institutions concern, and we have seen a great deal of advisory work arising out of this. We are beginning to see some institutions take a more critical look at the requests being made of them and have seen a greater appetite for challenging the decision-making behind the requests. We expect to see a growth in this area over the next few years.

We have not seen a particular rise in instructions to enforce foreign judgments. The Cayman Islands generally abides by the common law rules of enforcement, and so, absent submission to the relevant jurisdiction, enforcement can be problematic.

**MCC:** *What should our readers know about litigation in the Cayman Islands and other offshore jurisdictions your firm represents?*

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**Litigation has taken a critical look at the manner in which investment vehicles have operated, particularly surrounding insolvency.**

— Simon Dickson



**Dickson:** Perhaps the most important point to be made is with respect to the infrastructure, which has been put in place to deal with high-value, complex litigation. The Cayman Islands court has a specialized financial services division, a court of appeal (of which a majority of the judges are former Lord Justices of Appeal from the UK) and a final court of appeal in the Supreme Court in London. The Cayman Islands has offices of all of the major offshore law firms and all the major UK accountancy firms. It follows that the jurisdiction is well set up to deal with any financial services litigation.

As Hayden points out with reference to the *Weaving* matter, the Cayman Islands tends to throw up some of the most hotly contested issues around corporate governance and operations. Indeed, much of the litigation we have been involved in over the last few years has taken a critical look at the manner in which investment vehicles have operated and the issues arising, particularly in the event of insolvency. Cases such as these and the intricacies they have shown, together with the day-to-day expertise brought by our finance, corporate and investment fund teams, allows us to remain not only at the forefront of investment fund litigation but at the forefront of the issues concerning the investment fund community.

**MCC:** *Where do the Cayman Islands fit in as far as businesses evaluating the various offshore jurisdictions? What are the relative strengths and weaknesses of the jurisdictions?*

**Isbister:** We operate as one firm globally. The British Virgin Islands, the Cayman Islands, Jersey and Guernsey are the preeminent offshore jurisdictions in which we wish to operate for the moment. Given our model and one firm approach, we are able to give clients a balanced view when considering structuring offshore.

**MCC:** *It depends on the type of work, doesn't it?*

**Isbister:** Yes, to a degree. If someone wants to start an offshore hedge fund, they often come to Cayman because it is recognized as a leading hedge fund jurisdiction, but if, for example, someone wants to just set up a basic holding company, they may look to go to the British Virgin Islands instead.

Cayman is constantly evolving. We are about to have Cayman LLC vehicles, which are based in part on the Delaware LLC. They will strengthen Cayman's position particularly for U.S. providers, promoters, managers and lawyers who may look to use Cayman LLCs in various fund and other corporate structures. It is expected that the Cayman LLC vehicle will be available in the first half of this year.



# IN-HOUSE OPS

## The True Rewards of Compliance

By Yogesh Bahl / AlixPartners LLP

*Ongoing maintenance and understanding the “bias blind spot” can boost compliance*

Although building a culture of compliance has been a goal and topic of discussion at many companies for several years, creating a sustainable culture of compliance requires that companies regularly re-evaluate compliance strategies and tactics. This helps compliance professionals remain vigilant and keep pace with inevitable changes in the business landscape, including regulatory, technological and other changes that impact compliance. Identifying new and fresh ways of getting management and employees to own compliance consistently in their day-to-day responsibilities remains a challenge. News reports on a weekly basis cite companies that have agreed to deferred prosecution agreements and corporate integrity agreements after compliance violations; consequently, we are reminded of the importance of the need to refine and improve upon existing compliance programs procedures wherever possible.

### CCI and Behavioral Studies

Continuously improving a company's compliance program (something I refer to as continuous compliance improvement, or CCI) is easier said than

done, since limited qualified talent and financial resources can lead a company to run their older compliance programs on autopilot for long periods of time. To better execute CCI, it is important to understand when, how and why an individual or a group of individuals may choose a path that leads to potential compliance or regulatory violations. Behavioral psychology can shed light on how employees address questions of right and wrong and better equip a company to design new and more effective compliance strategies. These improvements can help management and employees make the desired choices at crucial ethical decision points.

### Understanding and Shaping Behavior

Duke University professor and noted behavioral economist Dan Ariely and other behavioral psychologists have conducted studies that show we all have some level of internal reward mechanisms that balance against external reward mechanisms.<sup>1</sup> Many regulations and policies tend to focus only on external factors like increasing the likelihood of being caught for an offense or increasing the magnitude of punishment. This only partially ad-

addresses the honesty/dishonesty equation in a compliance context. The persistent conflict between an ethically correct self-image and responding to opportunities to advance self-interest continues to attract serious study and has concrete application

### Behavioral psychology can better equip a company to design new and more effective compliance strategies.

to helping businesses with compliance issues.<sup>2</sup> In addition, this body of academic work can be used to better understand how to influence behavior and provide legal and compliance departments with more ideas to facilitate CCI. As examples, companies can consider two important concepts to better refine their compliance strategy and tactics: timing of value reminders, and bias blind spots.

### Recent Value Reminders

To facilitate CCI, the first concept emphasizes staying connected to an established set of values. Ariely's studies show that, when given a recent reminder of our morality and our values, we are more likely to do the right thing during ethical decision points; a company can incorporate this concept to facilitate CCI. For example, some companies may provide compliance training once a year, which may not be sufficient based on behavioral studies. As the balance between our internal reward system and external reward systems is better influenced via recent reminders of acceptable values, a company, for example, may consider adding short, five-minute compliance videos or discussions at the end of selected meetings throughout the year. In addition, instead of compliance posters with explicit language on “doing the right thing,” these posters may

have more impact if they have images of family members helping each other and include value-based messaging, i.e., provide a subtler reminder of the values the company wants to espouse.

### The Bias Blind Spot

The second concept relates to research by Eddy van Averaet on unintentional bias, which suggests that although people will generally abide by what is fair, when given a choice, people will take actions that are biased in their favor in lieu of maximizing the outcome for someone else.<sup>3</sup> In addition, related research indicates that, even after providing training on their unintentional bias, people are better equipped to recognize bias in others and not in themselves.<sup>4</sup> This inability to recognize bias in ourselves is referred to as a bias blind spot and has many implications in the compliance profession. For example, one may conclude that the bias blind spot would support the argument that rewards for whistle-blowers provide an incentive for employees to report the actions of other employees to external parties before reporting the actions internally at the company; this would be the best way in whistle-blowers' minds to maximize their benefits. Therefore, it would be a better compliance measure to provide incentives and policies to report the action internally so that the company can first attempt to address the issue before the employee goes to an external party. As another implication of the bias blind spot, consider compliance training. It may be argued that compliance training may help employees recognize the actions in others rather than influence change in their own actions. If this is the case,

*Continued on following page*



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## Compliance

Continued from previous page

one can consider compliance-related training just as much a monitoring tactic as a prevention measure. Further, this would make compliance training more integral to monitoring measures, such as the management of complaints made by employees.

Understanding and addressing the cognitive buffers that may obscure

ethically or legally problematic behavior may be difficult to do with precision, but the use of value-based visual cues and steady reinforcement of desired behavior is supported by ample research concerning its role in perpetuating CCI. When maintaining a compliance culture bound by a multitude of regulations, the carrot of supportive, self-reinforcing reminders of values and be-

haviors that inhibit transgressions may be more effective and adaptable than the stick of after-the-fact punishment. Further, by addressing the behavioral component – how employees deal with issues of right and wrong – companies can develop strategies to help employees make the desired choices when faced with a decision that may impact compliance. Most importantly,

improving a company's compliance efforts should be a continuous process aligned with changes in the company's business strategy and rooted in an understanding of the people who guide organizational behavior.

*The opinions expressed are those of the author and do not necessarily reflect the views of AlixPartners, LLP, its affiliates, or any of its or their respective professionals or clients.*

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# Tackling the Human Element in Transformation

*Nothing will change until your people do*



**By Lloyd M. Johnson Jr. / Chief Legal Executive LLC**

**W**hen thinking about transforming the legal department into a strategic partner for the business, it helps to see it as a journey rather than an overnight change. And Nancy Jessen, senior vice president of Legal Business Solutions at UnitedLex, breaks that journey down into four increasingly sophisticated steps.

Jessen explains that law departments need to evolve from simply providing substantive legal knowledge to having business acumen; to efficiently and effectively providing value-added services to the business; and providing corporate leadership and contributing to company strategy and success.

If a law department is to complete this journey, the people who make up the department have to evolve along that same continuum. That is, they need to change. And as anyone who has worked to transform an organization will tell you, people's resistance to change is often the biggest obstacle along the way. In reality, people don't dramatically change the way they think and work just because their boss announces that they should. So it is up to the general counsel to foster, encourage and drive that change.

The question is, how do you do that? Carey O'Connor, senior vice president, general counsel and secretary at Flowserve, the Dallas-based global provider of pumps and other flow-control products, has been working on just that issue. In her push to transform Flowserve's legal department – and enable change across her 85-person staff – she has learned some valuable lessons about what works when it comes to the people side of transformation.

## **Sell the Change**

To begin with, O'Connor cites one of the fundamentals of effective change management: You have to make the case for change and paint the big picture of why the department needs to adopt new approaches. However, she adds, it's critical to sell change at the individual level as well. "It is important to sell employees on how the change will improve their daily work experience, not just on how the change benefits the company," she says. "For example, if one of our attorneys wants more work/life balance, I will discuss how optimizing the work we perform, if done correctly, will help him or her have more control over their schedule."

O'Connor also focuses on helping employees broaden their perspective on the legal work they handle so they can learn how to think outside the box in terms of how to manage the work more efficiently. Instead of simply telling people to reduce costs by  $x$  percent or speed up work cycles, O'Connor recommends having individual discussions that help employees understand what it means to be more efficient and effective and, ultimately, focus on higher-value work. "Employees rarely think they are not efficient, so telling someone to just do more work in less time can cause a credibility gap between you and your employees," she says. "I have found it is more effective (and, frankly, more fun) to brainstorm with them on how we can perform work differently. It gives us an opportunity to be creative and to be proactive in how we manage our work, versus always reacting to the work we are given. This helps employees feel they have a greater ability to manage their workload versus the work managing them."

## **Tie Change to Career Paths**

Of course, part of the overall message should be that people need to change if they want to advance their careers. "General counsel do not promote lawyers based on substantive legal knowledge," O'Connor says. "That's just not what the job is about. Being an in-house attorney is about solving business problems in a proactive, efficient manner. Substantive legal knowledge is important, but we consider that table stakes for our lawyers. A successful in-house attorney needs business acumen and organizational awareness in addition to functional legal expertise. This is particularly true for anyone who wishes to lead a legal department."

In essence, the general counsel can make it clear that staying focused on that first level – legal knowledge – is a recipe for a stalled career. And helping attorneys understand where they

are on that evolutionary continuum can lead to some aha moments. That was evident at a recent meeting where Nancy Jessen presented her transformation stages. One attorney looked up with surprise and said, "Oh, no – that's me. I'm stuck at the 'legal knowledge' level and not growing." She was not alone in that reaction, and that kind of awareness can help people get unstuck and change.

## **The Process Mind-set**

To enable people to change, it's also useful to foster a process-oriented mind-set, because that can shift the focus from doing things right to doing the right things – that is, to higher-value work.

Attorneys tend to think of their work in terms of complete, monolithic tasks – reviewing a contract or filing a lawsuit – rather than a process. But most legal work involves repetitive processes with multiple steps, and getting people to understand that can help them improve and move ahead. "Optimizing a legal department requires a leader to see how each area of legal responsibility – contracts, litigation, intellectual property, M&A, labor and employment, etc. – involves repetitive processes, regardless of the specific facts or location of the legal work," O'Connor says.

For example, when one is defending against a lawsuit, the facts behind the lawsuit will differ and the jurisdictional requirements may change, but the core work flow will essentially be the same. "No matter in which country the lawsuit was filed, the work flow for handling the lawsuit is essentially the same. You have to hire local counsel, assemble and present the facts, evaluate the chances for success, and decide whether settlement is appropriate," she says.

Having a process-oriented mind-set can help people see their roles differently. It makes it possible to break work down into component tasks and then, say, allocate routine tasks to paralegals or other legal staff, allowing in-house attorneys to focus on strategic issues linked to business outcomes. It also provides a more granular view that helps attorneys identify and eliminate redundant and inefficient work.

## **Learning to Prioritize**

O'Connor also helps her legal team improve their ability to operate effectively through a "rating and ranking risk" exercise. Here, legal employees brainstorm to identify hypothetical legal problems that could arise. The group then plots these threats on a quadrant based on two variables: the probability of the event occurring and the level of impact that it would have on the company. The result: insights into which issues the department should focus on.

However, O'Connor has found that legal staff frequently struggle to prioritize legal risks and typically start by rating all risks in the upper-right high probability/high impact quadrant. There is no prioritization; everything from processing routine employee immigration paperwork to a catastrophic, lethal product failure is given the same weight, which is simply not a reflection of reality.

"People have difficulty recognizing that some aspects of our legal work have a higher priority than others," O'Connor explains. "It is important to help them understand that rating a risk in a medium- or low-impact quadrant does not mean we do not value the work or that we will ignore the work. Instead, I encourage them to use the information to determine how to distribute work within the legal department." Forcing some degree of prioritization can help people shift their perspective and understand where their talents are needed most – and, perhaps, identify things that can be outsourced or delegated to external law firms or in-house paralegals so the attorneys can focus on the more business-critical problems.

## **Why Do All This?**

If overcoming reluctance to change sounds difficult, that's because it is. "Driving substantive change with lawyers and legal personnel (who frequently dislike change) is a time-intensive process. You have to be very hands-on and discuss your vision in both group and individual settings over and over and over," O'Connor says.

But those efforts can pay off. Over the course of two years, O'Connor says, her leadership team has gone from managing its work in silos on a reactive basis to greatly improved cross-team collaboration and a deep understanding of the importance of work prioritization. Her team is now highly valued by the company's business leaders as strategic partners. When she recently proposed changes to the process her team uses to review global customer contracts to reduce legal spend, the business leaders pushed back, arguing they needed more legal support, not less. The business leaders understood the value the contracts team provided in negotiating with customers, and they felt that the overall value they received from current legal spend was a bargain.

That kind of support points to a clear corporate leadership role for O'Connor's department – one in which the legal team, with the general counsel as mapmaker, is helping the business see over the horizon. And it points to the kind of results that general counsel can expect when they work proactively, and hard, to help their people change.

*Lloyd M. Johnson Jr. is chief executive of Chief Legal Executive LLC, a company that brings together thought leaders in the legal industry to discuss critical issues at conferences and events. He can be reached at [lloydj@chieflegalexec.com](mailto:lloydj@chieflegalexec.com).*

# Litigation Support Requires Both Talent and Technology

*Document review works best when all players can bring their skills to the fore*

**W**ith over 30 years of litigation support experience between them, **Al Sisemore** of **Inventus** and **Janelle Eveland Belling** of **Perkins Coie** have seen an evolution in both managed services technology and techniques. In this interview they discuss their strategies on delivering successful and efficient outcomes to their clients. Their remarks have been edited for length and style.

**MCC:** Please give our readers a brief overview of your backgrounds in managed review.

**Belling:** I have more than 20 years of experience in litigation support, 18 of which have been with Perkins Coie's e-discovery support team. I've held integral roles in the development and continued management of our document review offerings since the inception in 2007.

From our firm's perspective, we have a practice group called E-Discovery Services & Strategy, or ESS. We've recently expanded our managed review centers. We've included managed review in Chicago and Phoenix, in addition to Seattle.

Our ESS practice uses a combination of technology with resources that we have being a global law firm to ensure our matters are handled with customized teams – for example, a team of attorneys supplemented with technology professionals who collaborate with industry-specific lawyers and our clients on managed review.

We focus on ensuring our review attorneys are proficient in industry-leading technology and that they understand the repeatable and defensible work flows that were designed by our technologists. We have extensive experience with litigation, governmental investigations, analysis of corporate documents and a variety of non-litigation document review. In addition, we offer a full range of foreign language review.

One of the ESS goals is to expand not only the substantive scope of the review projects, things like due-diligence work, but also our geographic scope. In addition to Chicago, Phoenix and Seattle, we will be expanding our services to China and want to continue to grow and expand. We know that our clients are doing business and have facilities around the world, so our goal is to be an end-to-end e-discovery provider no matter where the data resides or the particular language they use in their communications. In order to do that, we know that we need to be able to assist with the discovery-related tasks regardless of the continent or the country.

**Sisemore:** I have ten-plus years of experience in litigation support, three years as a project manager when I first started in the industry and seven-plus years as a sales professional. I've been with Inventus for about 18 months. While my primary focus is on consulting for e-discovery services and technology, the majority of the matters I've worked on in the past have had a review element, so I've had various levels of involvement with managed-document review. From a company perspective, domestically, we work with partners for document review, like Perkins Coie. However, internationally, we do provide our clients' document review directly. We have performed managed review in 20 jurisdictions and reviewed documents in 21 languages in the last few years alone.

**MCC:** When you're working with corporate legal departments, what are your first steps, and how do you help them prepare for the process?

**Belling:** One of our first steps is to understand the specifics of the matter. We want to know our client's goals and any deadlines or requirements that we need to meet. We also want to make sure we're taking into consideration our corporate clients' information systems and then clearly establishing the role in managed review that our client is going to be playing. It's important that our team is complementing our clients' efforts.

Additionally, a plan for meeting and managing their expectations, establishing review deadlines and addressing budgets will be established. It's really important for us to develop clear roles and responsibilities and create that managed review plan to ensure everybody understands what's expected of them and the impact their role may have on the success of the review.

Finally, we're not simply focused on finishing the document review; we want to ensure that our clients and attorneys representing our clients are learning relevant facts from the document review. We need to understand their goals prior to, during and post-document review. If applicable, case analysis, hearing and deposition preparation, etc. can be incorporated into review work flows to increase the efficiency and decrease the redundant review that often results, thus reducing cost post-document review.

**Sisemore:** We share that perspective. I would add, too, that collaboration early in a process is an important piece. As an example, Inventus is handling the collection, ECA

processing and hosting services. It's important to establish an open line of communication and discuss the specifics of how data is going to be handled throughout the process. The end goal is to significantly reduce the amount of documents that need to be reviewed, ultimately reducing review cost. Establishing best practices and work flows at the onset of a new matter will help ensure that we meet this goal.

**MCC:** Going into managed review, who are the key players, and what are their roles? Who are your key contacts within the corporate legal departments?

**Belling:** At Perkins, we initially collaborate with in-house counsel and our Perkins Coie attorneys. Once again, we want to understand their goals and their role in managed review. Our

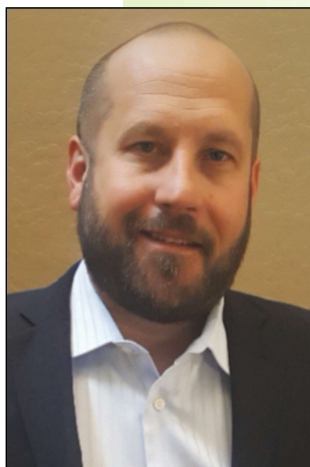
typical managed review team is going to have a combination of our client and attorneys from Perkins Coie, as well as some key roles within our E-Discovery Services & Strategy practice group. In particular, we have a lead attorney responsible for managing the review attorney team. They provide the regular updates on pace, progress, keep everybody apprised of budget, etc. The lead attorney works very closely with our technology professionals and consultants to ensure that the appropriate technologies are being used, that quality control is being implemented in real time, and that the technology is being fully leveraged.

Once again, roles and responsibilities are established and clearly defined. This is especially important when there are multiple parties with critical roles and competing demands and deadlines that could potentially impact the success of a review. One person's misunderstanding of their role and responsibilities might lead to a missed deadline. Roles and responsibilities should be established and documented before the review starts. It's also important to share them with clients, service providers or anyone else involved that are considered critical to success. This allows everyone the chance to identify areas that may need additional clarification. These steps help to ensure everyone is successful in their role, thus resulting in a successful and efficient document review.

We also understand that value is often shown through what we deliver and report during and after managed review has concluded, as well coming in under budget. We work with our clients to identify the reporting and deliverables required to ensure that we're meeting their expectations and delivering what they need, when they need it. Our work flows and technologies allow us to provide real-time reporting and customized post-project deliverables.

**MCC:** What are the skills needed by the legal and technical professionals to execute a successful and efficient managed review? With the rapid advances in predictive coding and artificial intelligence, what kinds of changes do you anticipate in the skills needed?

**Belling:** The advanced use of analytics and predictive coding should be standard, in my mind, on most if not all matters. Even if you're only using it to prioritize your



**We're leveraging best-in-breed technology along with custom-developed work flow to help streamline the process.**

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**The advanced use of analytics and predictive coding should be standard, in my mind, on most if not all matters.**

review and considerably enhance the quality of the review decisions. With data volumes exploding and an obligation to be efficient and save our clients money, technology needs to be deployed to increase the pace, to improve the consistency and to identify ways to quickly demonstrate our value by bringing key documents, issues or other topics not considered to the attention of our clients and the attorneys we support.

Analytics and predictive coding provide attorneys and technologists a catalyst to identify and feed key and relevant data and facts to our clients in real time, rather than waiting until the review is complete. Additionally, they allow us to validate data sets for review and identify methods to further reduce the data set that might be highly irrelevant. In my mind, technology should be leveraged with quality, pace, consistency, defensibility and cost reduction in mind.

**MCC:** *We've been hearing a bit about reviewing these new alternative communications, like Slack and Skype texting, that a lot of companies are introducing. Is that a trend that you're seeing, and do you feel that you have the technology to work with that?*

**Belling:** More and more, we are seeing various chat communications, especially in investigations. We have been vetting some new technologies that allow you to integrate/thread chat and other text messaging together with email. Finding technologies that can take a variety of communications and meld them together so we can see the story is essential.

**MCC:** *How do you and your teams work with clients to control costs? How do you determine what information is relevant and needs reviewing? How do you balance the need to control costs and mitigate risk?*

**Belling:** We're aggressive with technology in early-case assessment and data culling stages. We want to ensure that we have performed data culling in a defensible manner. We also want to make sure that we're getting it down to the smallest volume possible before we're engaging in the review. We know that document review is a very expensive process, and so we are very focused early on to make sure that we are reducing the amount of documents that require eyes on review.

A combination of analytics and predictive coding allows us to validate search terms, identify and locate relevant data that may have fallen outside the traditional search terms, and understand key concepts in our data even before the review begins. We also use technology to limit email that requires review by only reviewing the unique email content. We typically see a 20 to 40 percent reduction in email alone. Additionally, by clustering related email and similar documents, consistency and speed simultaneously improve.

Those techniques, along with prioritizing the documents based on predictive coding results, dramatically decrease the cost and time associated with document review. The joint simplicity of our repeatable and defensible work flows and the complexity of our proven techniques control cost, reduce risk, improve quality and accelerate our delivery.

I think it's important to mention that we see our relationship with top-notch vendors such as Inventus as a partnership. We look to their technology experts to augment our team. We encourage Inventus to help us refine our work flows or enhance the technologies that we're using to ensure that we're jointly successful at achieving our client's goals. I appreciate that Inventus understands our desire to identify methods to increase efficiency, save our clients money, and mitigate risk. I value the relationship and partnership that we have with them.

**Sisemore:** I couldn't have said it better, and I also value our relationship and partnership with Perkins Coie. To expand a little bit on what Janelle said: From the Inventus perspective, we view all of our client relationships as partnerships with the end goal of becoming a seamless extension of their team. Developing a true partnership lends itself to collaboration when identifying the best possible solutions, work flows and technology to efficiently accomplish the client's end goal.

Then to briefly touch on the technology component Janelle mentioned, it's really an important component when trying to reduce costs and mitigate risk. We're leveraging best-in-breed technology along with custom-developed work flow, middleware and stand-alone platforms to help streamline the process. Our e-discovery ecosystem, Luminosity, which is built in and around LAW PreDiscovery and Relativity, includes

technology such as inVerito, which is our custom ECA work flow within Relativity; M3 or Multi-Matter Management, which allows us to reuse or repurpose data and attorney work product across multiple matters.

We also deploy things like Advanced Logix, which programmatically puts a document review on guardrails. We also have auto

privilege log generator. This is the Inventus solution to automating the creation of privilege logs. Finally, we developed Spotlight, which is a business analytics dashboard that provides real-time visibility into all the key metrics our clients need. When developing these partnerships with firms like Perkins Coie and clients, we're giving them this enhanced technology to help better reduce costs and mitigate risk.

**MCC:** *This goes back to the new data sets, but more on the front end. What trends are you seeing in new data sets or communications that are included in the review process, and how do you help your clients prepare information governance policies for these new platforms?*

**Belling:** We are looking for trends in how people are communicating within a data set. Communication trends help us identify people that may be involved in a matter that we might not have known about. We want to be able to see changes in when and how people are communicating. They can assist us in identifying key concepts or themes that are in the data set that could help us prioritize the review and enhance the document analysis.

We're focused on using technologies that tie together the countless ways our clients communicate, for example with email, text, instant messaging, chat groups, et cetera. It can be difficult to tie together various forms of conversation and really understand how they are truly communicating. With that said, weaving those forms of communication together is essential for us to be able to tell the story.

Also, it helps us fully understand the matter from a communication thread perspective. If we see the communications weaved together chronologically when we're conducting a document review, we're making smarter and more consistent review decisions. With so many varieties of communication, we're needing to stay on top of it and figure out how we mesh them together and how we make sure that we're pushing those communications clustered together in an organized fashion to our review teams.

Additionally, we use technology to assist in preparing an outline of the scope of our client's data and information. We want to be able to identify how it's stored and organized, accessed and regulated. That knowledge supports efforts for us to identify their retention, preservation and production obligations.

**Sisemore:** I think Janelle hit the nail on the head. From a service-provider perspective, it's important for us to continually be looking at new technology, emerging technology, and understanding how to implement it with our existing technology and ultimately again help our clients to, or enhance our client's ability to deal with these emerging technologies in communication. It's imperative for the service provider to continue to vet those new technologies and have those as offerings for our partners and clients.

**MCC:** *What changes are you seeing in the courts and the litigation process as a result of the recent changes to the federal rules of civil procedure?*

**Belling:** Well, first of all, I'm not a lawyer, but I have personally observed the effect of the recent rule changes on the managed e-discovery process. The goal to introduce proportionality into the e-discovery process and the requirement of the parties to be transparent and cooperative in the e-discovery process provides an argument for technology and appropriate expenses related to the e-discovery process.

Parties are now encouraged to discuss e-discovery in advance of review and production and far in advance of even collection. It's increasing the collaboration and cooperation between parties. Further, with courts now endorsing the use of technology-assisted review and other analytical measures to reduce the burden and decrease the cost, the conversation with opposing parties is a much easier one today. From my perspective, speaking as a technologist, it's a much easier conversation with our clients and the lawyers that we support, as well.

# Email by the Numbers

*Graphing a department's email activity can yield crucial information on productivity and value*

**By Rees Morrison / Altman Weil, Inc.**

General counsel want to know about the legal department's productivity, value and client engagement. Even better, they welcome ideas regarding how to improve those important attributes. The good news is that insightful clues to each of them are as close as the email inbox! General counsel who understand and interpret data about the email traffic sent by their lawyers to internal business clients and received by their lawyers from clients have tapped into a trove for analysis. This column sketches how to collect that email traffic and ways to analyze it.

## Is It Legal?

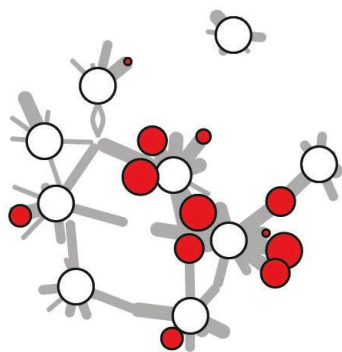
As readers might be concerned about invasion of privacy, my assumption is that all email handled on a corporate server is owned by the corporation and can be studied by the corporation. Hence, there should be no expectation of privacy regarding the emails of lawyers or clients. Point two is that the email traffic to be examined would be stripped of any content other than names of lawyers and clients and dates. Point three is that the data source will only be messages between corporate clients and their in-house counsel. (Whether attorney-client privilege would be threatened is beyond this column.)

## What Is the Email Data?

Here is more about the potential data set. An IT person could extract from the mass of emails only those from or to in-house counsel, only those in which corporate employees were writing to or hearing from those counsel, and those sent only within a defined time period, such as the past 12 months. For that subset of corporate emails, the general counsel would know the date of an email, who sent it, who received it, whether there were attachments, and the names of recipients

who were copied on the message. You would not know the name of any attached files or the subject or anything written in the body of the email.

All the emails that meet the criteria would be formatted as a spreadsheet with one row for every email sent or received by a lawyer in the department. It would be a large spreadsheet (although minuscule compared with what would legitimately be called Big Data). Assume a typical in-house counsel sends 10 emails each day to clients and receives 10. The legal department's intracompany volume, excluding intralaw department exchanges between lawyers or paralegals, would therefore be about 50 emails a day, or 350 a week and nearing 20,000 a year. That's how many rows might be in the spreadsheet. (We are leaving out instant messaging and chatting back and forth, by the way, but if those exchanges could be captured like email they could yield similar insights.)



## How Can You Visualize the Data?

It is not difficult to portray the tendrils of messages to and from people. Analysts can create a "network graph" that shows how many clients a lawyer emails with during the given period. The thickness of the line (the "edges," as they are called in graph theory) between the "nodes" (or data points, in this case the people corresponding with one another) would indicate the number of emails exchanged during the time period by the node correspondents. The color of the nodes (lawyers and clients) could correspond to corporate levels, e.g., VP, manager. The graphic depicts a bit of a network visualization.

Assuming software analyzes the data, such as open-source R, Tableau or Excel, what might a general counsel learn from the

data? Let's focus on the fundamental attributes of law departments noted at the start: productivity, value and client engagement.

## Productivity?

One inference you could draw from this data would be the simple one of approximately how much time each lawyer devotes to email. You could not simply calculate the number of minutes between receipt of a message and reply, since a lawyer might go off to a meeting or have lunch. But it would be possible to sample some emails and come up with an assumption – such as four minutes to craft each email – multiply the assumed constant by the number of emails sent, and divide that by the number of hours in the period of time worked. Three hundred emails in a month times four minutes equals 20 hours, which is 12.5 percent of a 160-hour work month. (Right, lots of emails are handled after work hours and on weekends, but you see the basic methodology.)

Email volume could also indicate which lawyers stay in their office, who gets out and talks or is in meetings, and who relies on telephone conversations (if you had data on telephone calls you could do a corresponding analysis and in the end match the two sources of data). Something meaningful might be gleaned from whether the email derives from a mobile device, a laptop or a desktop, and whether the message was sent from the office, but those complexities await another column.

It is possible to calculate turnaround time for messages based on when the reply went out. This would be a very crude measure because lawyers respond immediately to only a fraction of their incoming messages (unless it is merely an acknowledgment – "Got it and will work on it"). Still, with such large numbers of data points, characteristics of different lawyers in terms of promptness would be evident.

Analysis could also show increases in email traffic during large deals or drop-offs – Friday afternoons, for example. Around major transactions and important deadlines you would expect a surge in messages. Stated more generally, the data set contains information about when emails fly.

## Engagement With Clients?

More important than sheer numbers of mail messages is a sense of targets. By targets we mean which clients accounted for the bulk of the traffic. For this purpose an analyst could combine messages

sent to a client with messages received from a client. You might differentiate where the lawyer was in the "to" line as compared with in the "cc" line.

Also, a more significant message would probably have attachments, e.g., the revised contract or a portion of a regulation. (The analysis could code email threads as having an attachment or not; threads might be identified by similar content lines.) A reciprocal and symmetric network graph would show email traffic coming from clients – them reaching out to the law department.

## Value Delivered?

Presuming you know the level of clients, you could color the edges or change their thickness or style (dashed, dotted, solid) to indicate the hierarchy within the corporation of those who write and receive emails. This analysis would give a clue to how well you are meeting the needs of your client. Put crudely, the more senior the client, the more leverage they have from receiving legal advice or services. If they communicate frequently with their lawyer, presumably they see value in doing so.

Likewise, if major transactions or issues were being dealt with, the email flow could corroborate that lawyers were focused on those higher-value concerns. Thus, value metrics can be derived from such metrics as the email traffic based on the hierarchy and bandwidth of clients served, the percentage of client-initiated emails out of all emails, and the congruence of emails with major matters worked on.

In summary, the email traffic of the department represents an untapped lode of information about productivity, value delivered and client satisfaction. Of course, once this technique becomes an accepted management tool, lawyers will try to make themselves look better according to whatever metrics they think are being measured. The worst measure would be sheer numbers of messages coming in or going out of a lawyer's mailbox; that metric would be easily gamed.

Done for all the in-house counsel during a window of time, the emails give you a fuller sense of which lawyers allocate their time to this form of counseling and the amount of that time, how high and deep into the client structure your law department serves, and whether the focus of the lawyers – as viewed through the lens of email traffic – provides a proxy of value delivered.



**Rees Morrison**

*A principal at Altman Weil who also leads General Counsel Metrics, which offers the largest benchmark report of law departments ever done.*  
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## MCC INTERVIEW: Chris Colvin / In The House

## Community First

*A specialized networking organization provides in-house counsel with opportunities to thrive*

**In The House** is a private networking community for in-house legal professionals founded by **Chris Colvin**, a partner with Eaton & Van Winkle, LLP. This fast-growing network boasts over 23,000 members, hosts networking events for members, and is launching a revamped website ([www.inthehouse.org](http://www.inthehouse.org)) and private online community for in-house counsel this spring. His remarks have been edited for length and style.

**MCC:** Please tell our readers a little bit about yourself.

**Colvin:** I sometimes joke that I'm a rocket scientist turned lawyer because I was an aerospace engineering major at Princeton, then went on to work for IBM, where I designed certain portions of the U.S. air traffic control system. Then I went back to law school to become an intellectual property lawyer. For the last 20 years, I've been a practicing IP and commercial litigation attorney at a variety of different firms and have also held in-house positions, from solo GC at several startup companies to an in-house IP litigation position at a Fortune 500 company.

**MCC:** What inspired you to create In The House, and how has the community responded to the organization?

**Colvin:** It essentially arose out of a career-long passion for professional networking. Going back to my days at IBM, I was always eager to get to know my colleagues, both within and outside of my organization, so periodically, I would try to get friends and other contacts together for monthly breakfasts, lunches, etc. When the social media revolution happened, I saw an opportunity to continue to create networking gatherings but do it in a more scalable and reliable way.

In parallel with that, I eventually became a partner at an Am Law 100 firm, and I found that networking was a great way to develop business as well. So as much as possible, I would network with in-house counsel. Once I started developing a decent-size client base, I began introducing my clients to other in-house counsel I knew, just as a way of encouraging them to network. What I discovered in that process was that there were

relatively few opportunities for in-house counsel to get together in a casual environment to meet their fellow in-house counsel at other companies. That's what led to the genesis of what today is In The House.

**MCC:** What types of events do you host?

**Colvin:** Typically, we have hosted monthly breakfasts and cocktails and quarterly general counsel dinners. We have also experimented with a variety of other types of events, like golf outings to PGA courses and skyboxes at professional sports games. I think in just about every case, those have gone well and have shown that there's a real need within the in-house counsel community for these types of occasions on top of the traditional networking events that we've hosted.

**MCC:** What kind of feedback are you getting from members? What rings true with them about the group and their experiences coming to the events?

**Colvin:** One of the most gratifying aspects of In The House has been that perhaps the most frequent comment has been, "Thank you for putting together this community where it's so easy for me to find other in-house counsel."

Our management team has adopted the mantra of "Community first" for ourselves, meaning that every move we make as an organization should place the interests and careers of our members first and foremost – if our members succeed as in-house professionals, we succeed as an organization.

We are fortunate that we have fantastic sponsors to support our events. They realize that our members are primarily general counsel and other high-ranking executives from law departments who are interested in networking with other in-house counsel and executive-level business people from other organizations. Our sponsors are also companies who believe in supporting the in-house counsel community and can provide real value to our members in terms of relationships and tools to help in-house counsel serve their companies more effectively and, ultimately, to be seen as a vital strategic resource to their companies.



**If our members succeed as in-house professionals, we succeed as an organization.**

**MCC:** What do you see coming down the pike for In The House?

**Colvin:** In the next few weeks, we will be launching a new website, which will reflect our new branding. We've been very fortunate to be able to bring in a professional management team with an aggregate of over 100 years of experience in legal technology, legal events and legal media, so that move is helping us to really develop our platform and our services in a way that I couldn't do in the early days of our organization, just as a lawyer sitting around a conference table at my law firm.

We are launching an online networking community that will essentially be a mirror image of the networking events that we've done over the last few years. Members will be able to exchange professional expertise, recommendations for outside counsel and other service providers, exchange leads on new job opportunities, and more. There's a blogging platform where they'll be able to blog about items of interest and start conversations about hot topics within the in-house counsel community. We're taking what started largely as an events program in our early days, and we're putting that online so that folks who either have less time to attend our events, or perhaps are in a more remote location where we haven't yet reached them with our events, will be able to participate actively within our community.

In the long term, our mission is to work within our in-house community and provide our members with the tools, relationships and information that they need to thrive in their careers. The power of in-house counsel is increasing as the importance of their function increases. In order to

succeed as an in-house counsel, it's increasingly important to be at the cutting edge, in terms of knowing what technologies are available to help make law departments more efficient, what outside service providers are available beyond the law firms that have traditionally served in-house counsel and what outside providers can supplement services that law departments have traditionally gotten from law firms.

We are laser-focused on career development for in-house counsel, so we're not holding ourselves out as a general-purpose bar association that does all of the things that a traditional bar association does, but instead we're really focused on career opportunities for in-house counsel, meaning that we want to help them both be the very best they can be in their current job and also map out a long-term trajectory in their careers so that they can continue that success.

**MCC:** Is there anything else you would like to share?

**Colvin:** As we grow and expand our offerings, we don't want to lose that element of fun that has been a key component of In The House since day one. I've always been someone who believes in mixing business and pleasure. We want our events, and we want our community, to continue to have that sense of fun and spontaneity, and that's really important to us. Starting with our name, we want to have a little bit of fun in our legal careers, and we think that it is really important to enjoy your job and to enjoy engaging with fellow attorneys and other in-house legal professionals.

I attribute our success so far to the fact that we constantly get feedback, both solicited and unsolicited, from our members. I think they're comfortable approaching me or approaching others in our management and telling us what they want from the organization. I think there is a real sense of ownership within this community – that we are a community by in-house counsel, for in-house counsel. We plan to continue to help our members make our community what they want it to be, now and for years to come. If we can do that, if we can achieve that goal of putting the "Community first" in everything we do, I hope and believe we'll continue to enjoy the growth that we've enjoyed thus far.

## Chris Colvin

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For more than 20 years the in-house community has relied on *Metropolitan Corporate Counsel* for leading-edge information focused on serving the world's leading corporate law departments by:

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- Supporting the legal, legislative and business goals of corporate counsel

The collage displays several issues of the *Metropolitan Corporate Counsel* magazine. The central focus is the July/August 2015 issue, Volume 23, No. 7, which features a cover story titled "FOLLOW THE MONEY: A NEW WAVE IN EXEC COMP" with a photo of Barbara Hackman Franklin, NACD President. Other visible covers include "Civil Justice Playbook" (Human Initiatives, Influence), "Regional Focus: INDIA" (MCC Interview: Anurag Varma & Shashi Anand), "IN-HOUSE OPS" (Advertising & Marketing), and "IN-HOUSE OPS" (No Dumping). The magazine covers a wide range of topics relevant to in-house legal departments, including corporate governance, risk management, and industry-specific insights.

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# Civil Justice Playbook

IDEAS, INITIATIVES, INFLUENCE

## This Court Means Business

In this column, we talk a great deal about reform of the civil justice system. It was a topic near and dear to the heart of *MCC*'s founder, Al Driver, who as former General Counsel of JCPenney had a very special interest in the subject. Search the archives of *MCC* on our website and you'll find no shortage of articles on the topic since the publication's launch in 1993.

Al also had a special interest in the Commercial Division of the New York state courts, another topic that frequently found its way into *MCC*'s pages during Al's stewardship. (Al retired two years ago.) Various authors, including Robert Haig, a partner with Kelley Drye & Warren and chair of the Commercial Division Advisory Council, and Timothy S. Driscoll, a Justice of the Nassau County Commercial Division, continue the tradition.

An outside observer – say, from Venus – wouldn't necessarily see the connection between civil justice reform and a state court system – especially a system in the nation's biggest city by a factor of two. Take a look at our January issue. We wrote here about a recent study and survey by the National Center for State Courts that painted a shocking picture of our state courts as dismal dead-end venues delivering a lopsided brand of justice that is feeding a “disturbingly pervasive belief in an unequal justice system.” The courts – not all of them, but many, particularly in our biggest cities – are driving litigants out of the system. This in turn has spawned efforts to redress the mess before it's too late.

Rebecca Love Kourlis, founder of the Institute for the Advancement of the American Legal System and a former justice of the Colorado Supreme Court, put it this way: “There is a national movement to make the courts more efficient, navigable and affordable,” she said. “The customers are demanding it. They are choosing to go elsewhere when they have a choice.”

Which leads us to Judith S. Kaye. Judge Kaye, retired chief justice of the New York State Appellate Court, died in January. Her greatness as a jurist and a court administrator did not go unnoticed. Indeed, a memorial service at Lincoln Center's David H. Koch Theater drew a who's who of mourners, with former mayor Michael Bloomberg leading the way.

“This elegant, classy, graceful debonair woman was a revolutionary,” Bloomberg said. “And the revolution she ignited has helped countless Americans get their lives back on track and stay out of jail and has spared countless more people from being victims of crime.”

The many tributes to Kaye focused, rightfully so, on her tireless efforts to keep criminals out of the courts – and to treat them with fairness and dignity when they were there. They also laser in on her status as the first woman to serve as New York's chief judge, and her 2006 dissenting opinion in *Hernandez v. Robles*, the New York same-sex marriage case that helped pave the way for the judicial sea change to come when she declared that “the long duration of a constitutional wrong cannot justify its perpetuation.”

Amid the homages from lawyers, judges and politicians was an article in the *Red Hook Star-Review*, the community newspaper of South Brooklyn, that we suspect would have especially pleased Judge Kaye. It's about the mean streets of New York in the late 1980s when both Red Hook and Times Square were suffering from savage crime levels. Starting on Broadway and continuing in South Brooklyn, some enterprising New Yorkers, including Judge Kaye, got behind an idea to improve public safety with community courts geared to solving underlying problems rather than slapping petty criminals in jail. The Long Acre Theatre on 54<sup>th</sup> Street, donated by the Shubert Organization, became the city's first community court, and the Red Hook Community Justice Center soon followed.

Not only did Judge Kaye put the full weight of her office behind the idea, she showed up, as the article recounts, in jeans to help whitewash the walls in preparation for the opening of the midtown court. Alex Calabrese, RHCJC's presiding judge, describes the transformation.

“Downtown,” he told the *Star-Review*, referring to his previous courtroom, “I only had two tools: jail and out of jail. Here I have a whole clinic.”

One aspect of Judge Kaye's career, however, received far less notice in the swell of tributes that followed her death. That's her ability to work the same magic with the state courts'



handling of commercial cases as she did with the community courts. New York City was at a low point as people and businesses fled. Lawyers and their business clients also were voting with their feet and turning to the federal courts whenever possible for commercial matters. The reason is that commercial cases were loaded onto the same general dockets as all types of other matters, including personal injury and negligence cases, choked the system. The courts were slow and poorly equipped. The business community was up in arms.

Haig of the Commercial Division Advisory Council sums up the frustration: “In 1995, when the Commercial Division first started, the prevailing attitudes in the New York state courts were that there were too many cases in the court system and not enough money, and that nothing could be done about it.”

Judge Kaye jumped in. “The reluctance of major companies to come into the state courts was related to the utterly overwhelming drowning dockets,” she said. In 1993, she formed four “commercial parts” in New York county dedicated to business cases. She populated them with judicial volunteers with special interest and expertise in such matters, and she transferred pending cases to the newly formed parts. Within two years, it was clear the experiment was succeeding. She formalized the model by establish-

ing a state court division, and various counties upstate and downstate bought in. With that, the Commercial Division was up and rolling. Looking back, the audacity of the ambition surrounding the project is breathtaking.

“What we envisioned 20 years ago,” says Judge Kaye, “was staying apace of world change.”

“We're the commercial center of the world,” adds Jonathan Lippman, retired New York state chief judge, “and our court should be not only world class, but a place where everyone understands that they can come and see . . . the right way to resolve a commercial dispute.”

The above comments are drawn from a video released, fittingly enough, around the time of Judge Kaye's death. A joint production of the Historical Society of the New York Courts and the Commercial Division Advisory Council, it features a series of over-the-moon testimonials from a who's who of bench, bar and business. While Martin Scorsese has nothing to fear cinematically, the video is worth a watch. It includes short statements about the Commercial Division from a string of legal legends, including Martin Lipton of Wachtell, David Boies of Boies Schiller and James Quinn of Weil, among many others. Of special interest to *MCC* readers are the many GCs who chime in – a group not exactly known for their love of the courtroom. They include Stephen Cutler of JPMorgan Chase, Douglas Lankler of Pfizer, and Michele Mayes of the New York Public Library. Have a listen:

“We've certainly lost our fair share of cases in the Commercial Division,” says David Ellen, General Counsel of Cablevision, “but nothing in any of those losses changes our view about the impressive characteristics of the Commercial Division – its open-mindedness, its conscientiousness and its integrity.”

“It was comforting to know that we had a court system that was familiar with the kinds of disputes that companies are involved with,” echoes Michael Fricklas, General Counsel of Viacom. “They understand economics. They have experience with complicated contractual language. They understand the importance of getting it right and following the rule of law.”

Gregory Palm, General Counsel of Goldman Sachs, adds an exclamation point: “I'd say the true mark of a successful specialized court is that both sides select the court as their preferred forum, and at least in our experience, that's been the case.”

The Commercial Division continues to evolve, with the Advisory Council leading the way in carrying out Kaye's vision of a future-focused court. In what likely was one of her last public acts, Judge Kaye appears in the video. Her sense of pride and accomplishment is palpable.

“New York law is so stable, so predictable, so sound and logical,” she says. “It's the courts that make it that way.”

## Backstory

BY LISA A. RICKARD

# Piling On: A Simple Matter of Injustice

*The following statement is from Lisa A. Rickard, president of the U.S. Chamber Institute for Legal Reform. She can be reached at 202.463.5724, [www.instituteforlegalreform.com](http://www.instituteforlegalreform.com).*

“All the great things are simple, and many can be expressed in a single word,” Winston Churchill once noted and cited “justice” as a good example.

While the concept of justice may seem simple, actually “doing justice” is often anything but.

Meting out justice to wrongdoers is critical for our democracy and free economy. Law enforcement is obligated to root out bad actors, present a case and seek a punishment that fits the alleged infraction.

In our global economy, however, there is a globe’s worth of enforcers. And thus the “simple” practice of doing justice becomes complicated.

The Great Recession of 2008 gave way to the most aggressive level of enforcement against companies of all shapes and sizes in modern history. The U.S. Department of Justice led an unyielding pursuit, raking in tens of billions of dollars in fines and penalties, all from settlements with companies.

The DOJ was not alone. Many other federal agencies, state attorneys general and regulators joined in – often against the same companies and for the same alleged infractions.

And pursuit didn’t stop at the water’s edge. Governments worldwide joined the rush to penalize companies from banks to insurance to pharma to manufacturing – each seeking its own cut.

But earlier this year, at a London conference of the world’s top financial regulators, the multinational “piling on” effect seemed less like justice and more like a growing problem. According to a *Financial Times* article, Andrew Weissmann, the U.S. DOJ’s chief of the criminal division’s fraud section, said, “There is a problem with piling up: [T]here is both a fairness issue but it’s also in law enforcement’s interest to do a better job.”

Mark Steward, chief enforcer at the UK’s Financial Conduct Authority and fellow London conference speaker, agreed, saying the world’s governments should discuss the problem of double jeopardy – serial prosecution of a company for the same alleged violation. He called for exploring an international treaty on the practice.

Prosecutorial “piling on” is a problem because the collective result of its multiple “punishments” is grossly distorted justice.

In the U.S., investigators have no obligation to prove a connection between the misconduct they allege and the settlement they demand. Settlement amounts are picked out of thin air. Multiply that amount by many government agencies, add in global prosecutors, and the dollars get massive.

Some say companies should fight excessive demands. They can’t. A loss in court is too risky and could mean the end for most companies. In addition, heavily regulated industries highly dependent on government licensing must maintain good relations with regulators to stay in business.

Ally Bank recently settled with the Consumer Financial Protection Bureau for \$98 million dollars over allegations of auto loan discrimination. CFPB documents recently released by the House Financial Services Committee show that the agency believed its own case was weak but used Ally’s impending bank charter renewal with the Federal Reserve as leverage for a large settlement.

CFPB’s own internal memo said: “As such, Ally may be strongly inclined to reach a timely and robust resolution of this matter if it can potentially result in Ally Financial Institute maintaining its current corporate status.”

At the London conference, the global officials fretted over whether high penalties weighed on banks’ balance sheets, causing them to reduce lending. This is the ultimate irony: Perpetual prosecution of financial institutions to ensure a stronger financial system may actually weaken those same institutions, undermining overall financial stability.

If justice is the primary motivator for these prosecutions, why is the “piling on” effect happening? Perhaps for some prosecutors, justice isn’t the primary motivation.

In 2014, former U.S. Attorney General Eric Holder stated that DOJ recovered more than \$24 billion in enforcement actions and that the department’s recoveries dwarfed its \$2.91 billion budget. Interestingly, DOJ is allowed to retain a percentage of what they recover in many cases.

Many state attorneys general compete with each other to see who can get the higher settlement, which they leverage for PR headlines that help bolster their political careers. Some even get to keep a large portion of the settlement to fund their offices; a few have even funded pet projects with settlements.

The “pile on” effect is unfortunately not new. But its global spread – and the recognition of harm to the world’s financial markets – may offer hope.

Growing international awareness of the “piling on” problem should be a catalyst to fixing it. This is important considering the international complaints that over-enforcement practices have hurt the U.S.’s business-friendly reputation.

Guidelines for coordination between and among domestic and international prosecutors are necessary. And these guidelines should seek to eliminate perverse economic incentives that are at the heart of too many of the current settlements.

It is high time that we establish fair standards for prosecuting wrongdoing. It’s a simple matter of justice.

*Perhaps for  
some prosecutors,  
justice isn’t the  
primary motivation.*



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After a quieter period, the Securities & Exchange Commission has renewed its focus on financial-reporting fraud. KPMG's Pamela Parizek and Howard A. Scheck address this shift in emphasis in SEC oversight and enforcement from their vantage point as forensic accountants who perform independent investigations and support audit engagement teams.

**MCC:** Why the renewed focus on financial-reporting fraud by the U.S. Securities and Exchange Commission?

**Pam Parizek:** Financial statement fraud has always been a core focus of the SEC's enforcement



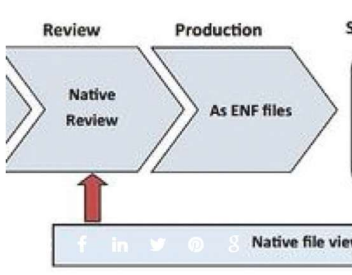
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