



U.S. CHAMBER  
Institute for Legal Reform

# Enforcement Gone Amok

*The Many Faces of Over-Enforcement  
in the United States*

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MAY 2016





**U.S. CHAMBER**  
**Institute for Legal Reform**

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# Executive Summary

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“One of the first purposes of government identified in the Preamble [to the United States Constitution] is to establish Justice through the offices of government. Our Bill of Rights and subsequent amendments to our Constitution reflect a strong tradition of guaranteeing due process and affording the equal protection of our laws to all citizens.”<sup>1</sup>

All elements of American society benefit when the legal system is used as intended by our Founders—namely, to prosecute and punish genuine wrongdoers whose actions have violated the law and caused injury or damage, guided by due process and the Eighth Amendment principle that the punishment should fit the crime. However, recent events have shown that government enforcement actions increasingly overstep reasonable bounds.

Over-enforcement occurs when individual government agencies exercise unfettered discretion to rely on novel or expansive interpretations of laws to coerce settlements. Companies that are targets of this practice cannot be certain that the courts will set aside these actions, given the often vague and broad statutory language that confers authority on these agencies.

Over-enforcement also occurs when the prosecution of wrongdoing is carried out by multiple regulators conducting duplicative investigations and legal actions, either simultaneously or in succession, which are directed at the very same conduct. Faced with these multiple assaults, companies often have little choice but to agree to whatever settlements those various government officials demand, even if the company has meritorious arguments against the underlying charges.

One consequence of both coercive and “pile-on” over-enforcement is large and duplicative fines and penalties that too often are disproportionate to the alleged wrongdoing. The fact that over-enforcement targets are typically corporations and not individuals does not excuse the abusive nature of the practice—“justice for all” must apply across the board.

Over-enforcement abuses have plagued businesses that run the gamut of American industry.<sup>2</sup> This paper highlights examples, drawing in particular from the financial services, pharmaceutical, and insurance industries, to shine much needed light on the wide-ranging and often interrelated ways in which the government has taken advantage of those who find themselves in the cross-hairs of an enforcement action.

From overreach and coercion employed by unbridled federal and state prosecutors, to “piling-on” by multiple federal and state government entities seeking their piece of the settlement pie, to punishment in the form of excessive fines and penalties, this paper examines the ways in which the enforcement process is being misused to the detriment of business and society as a whole.

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# Abuse of Discretion: Prosecutorial Overreach and Coercion

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Enforcement abuses can occur at the hands of a single prosecutor whose unfettered discretion can breed unsavory results. Prosecutors have discretion in deciding which companies and industries to investigate, and that discretion is subject to abuse when prosecutors pursue high-profile companies and sensationalist stories to bolster their “winning” records, or when they seek to advance the interests of a minority of politically influential citizens or plaintiffs’ lawyers.<sup>3</sup>

Prosecutors also have tremendous discretion in determining which of the myriad laws and regulations they have at their fingertips to apply in a particular case. The fact that many of these laws are vague and broad amplifies the potential for abuse, providing an opportunity—albeit a dubious one—for pursuing novel legal theories.

In addition, the desire of prosecutors to counteract cuts to their respective budgets can lead to the stacking of charges and the pursuit of the highest possible criminal or civil penalties, regardless of whether the charges or penalties are justified by the evidence in a case. As prosecutors retain the proceeds of settlements generated from enforcement actions for their own offices or preferred charitable programs, they acquire

a “private interest, so to speak—in the outcome of the case.”<sup>4</sup> Indeed, “[e]ven if the [prosecutor] carefully considers the public interest in the enforcement and continues to weigh all the costs, the conclusion of its cost-benefit analysis may be different given the new interest on the scale,” which will auger “in favor of action.”<sup>5</sup>

And finally, prosecutors have an immense degree of discretion in determining which conditions of settlement to impose on vulnerable companies willing to settle, whether through plea bargains, consent decrees, or other injunctive relief.

The following examples illustrate some of the abuses that stem from unchecked prosecutorial discretion.

## Threat of Litigation as an Inducement for Settlement

The government has unique leverage to push settlement on companies fearful of the reputational and monetary costs that inevitably surround a protracted, highly-publicized litigation. Even where the “threat” of trial is not overt, the inherent uncertainty of litigation and its collateral consequences tips the settlement scales in favor of the government, permitting it to dictate the terms of the resolution. Examples drawn from the pharmaceutical industry illustrate this phenomenon and its obvious perils.

### OFF-LABEL PROMOTION

The federal Food, Drug and Cosmetic Act (FDCA) prohibits pharmaceutical manufacturers from engaging in “off-label” promotion of their products for uses not previously approved of by the federal Food and Drug Administration (FDA).<sup>6</sup> Historically, the FDA has regulated off-label promotion moderately by issuing regulatory warning letters and violations. In recent years, however, “the DOJ has emerged ... as a more ‘strident crusader’ in searching for violations of the off-label marketing regulations,” bringing along with it the threat of a criminal felony charge against those who directly promote drugs for off-label uses.<sup>7</sup>

The collateral consequences that follow from a criminal felony conviction include exclusion from doing *any* business (not only limited to the product at issue) through federally-funded healthcare programs such as Medicare and Medicaid, often referred to as the “corporate death penalty” for

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pharmaceutical companies.<sup>8</sup> Given the severity of the consequences of such a conviction, the government holds a strong hand in achieving settlement of off-label promotion and misbranding claims, regardless of their merit.

Complicating the compliance picture for drug manufacturers is the fact that current FDA regulations lack specificity with respect to what conduct is and is not permissible in the promotion of a pharmaceutical product, leaving a great deal of room for prosecutorial interpretation and abuse. The government has recently attempted to expand its enforcement power in the arena of off-label promotion. The investigation into Eli Lilly’s sale of the drug Evista is a vivid example of a growing trend: the Department of Justice (DOJ) increasingly scrutinizing practices not traditionally investigated or evaluated by the FDA, including the use of continuing medical education, advisory boards and consultants, incentive compensation,



market research, business planning documents, and company responses to unsolicited requests for information.<sup>9</sup>

Further complicating the regulatory and legal landscape is the fact that the FDA does not prohibit physicians from prescribing medicines for off-label purposes; rather, it merely prohibits drug manufacturers from promoting their drugs for unapproved uses.<sup>10</sup> Indeed, the FDA has recognized that prescribing drugs for other uses is legal and often beneficial; physicians, researchers, and patients are free to give presentations on off-label uses of drugs, discuss them formally, or publish papers documenting their findings in medical journals and the press without regulation by the FDA.<sup>11</sup> The dichotomy between allowing off-label promotion on the one hand, while banning only the manufacturer from communicating about those uses on the other, highlights the extremity of the sanctions imposed on pharmaceutical companies for conduct otherwise encouraged as being in the public and medical community's best interest.

Recent enforcement actions related to off-label promotion have involved allegations that the drug company at issue had strategies in place to support off-label

studies, with the goal of using the results of those studies to promote the product for unapproved uses. Investigations and prosecutions often involve allegations that the manufacturer has selectively published positive results of such studies.<sup>12</sup> While prosecutors see these business practices as evading FDA regulations requiring formal approval of new uses for drugs, there is arguably a free speech component to such company publications and promotional activities. In fact, in *United States v. Caronia*, the Second Circuit Court of Appeals held that while "misbranding" a pharmaceutical product is beyond the scope of the First Amendment, "truthful, non-misleading off-label promotion" is constitutionally protected as commercial speech.<sup>13</sup>

In so holding, the Court of Appeals recognized that "off-label drug *usage* is not unlawful, and the FDA's drug approval process generally contemplates that approved drugs will be used in off-label ways."<sup>14</sup> In other words, "even if pharmaceutical manufacturers are barred from off-label promotion, physicians can prescribe, and patients can use, drugs for off-label purposes."<sup>15</sup> According to the court, criminalizing off-label promotion

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while simultaneously allowing doctors to prescribe drugs for off-label uses “paternalistically interferes with the ability of physicians and patients to receive potentially relevant treatment information[.]”<sup>16</sup> Still, notwithstanding the Second Circuit’s pronouncements, federal prosecutions in this arena are continuing. As one commentator has observed, “[w]hereas pre-*Caronia* [press] releases [by the government] tended to only mention off-label marketing or promotion when discussing ... recoveries, post-*Caronia* releases ... have included references to ‘misbranding’ as well .... This subtle, but significant, inclusion perhaps telegraphs that the Government does not currently view *Caronia* as much of a threat to its successful ... off-label cases.”<sup>17</sup>

### **ELI LILLY’S EVISTA PLEA AGREEMENT**

In December 2005, Eli Lilly agreed to pay \$36 million for allegedly illegally promoting the drug Evista, and pled guilty to a criminal misdemeanor violation of the FDCA for misbranding the drug.<sup>18</sup> Evista was approved by the FDA for the treatment of osteoporosis in post-menopausal women. According to the government, after Evista’s disappointing sales during its first year on the U.S. market in 1998, Eli Lilly began to promote the drug for off-label uses, including the prevention and reduction in the risk of breast cancer and cardiovascular disease.<sup>19</sup>

The government’s primary bargaining chip in securing Eli Lilly’s guilty plea was the looming threat of a potential felony conviction and subsequent exclusion from participation in federally-funded healthcare programs. Pleading guilty to a misdemeanor

and agreeing to comply with other demanding requirements of the consent decree allowed the company to avoid a felony conviction and continue selling products covered under federal health insurance programs. As the attorney for Eli Lilly stated, “[w]e had to find a way out of that box.”<sup>20</sup> The attorney responsible for helping to craft the misdemeanor plea noted that it was one of the first such pleas.<sup>21</sup>

As a condition of the consent decree and in order to avoid a felony conviction, the government imposed rigorous, long-term obligations on Eli Lilly with respect to Evista. For example, the consent decree required the company to implement additional training and supervision of its marketing teams and to ensure that any future off-label marketing conduct was detected and corrected. Eli Lilly was also required to provide the government with quarterly reports on interactions concerning Evista between sales representatives and physicians. Furthermore, the consent decree required Eli Lilly to submit all market research conducted by the Evista marketing team to the government, a novel requirement in the arena of off-label promotion litigation.<sup>22</sup>

The costs of compliance with such consent decrees in the pharmaceutical industry can be astronomical, far exceeding the punitive fines imposed for the specific behavior at issue. These additional costs, including payments to outside consultants, require money that could have been used for research or new drug discovery.<sup>23</sup> Other related long-term negative side effects include “tarnished reputations, lost sales,

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massive fines and remediation expenses, hostile working environments, diminished morale, legal disputes, employee retention problems and product shortages.”<sup>24</sup>

Notably, the demands of the consent decree were imposed on top of Eli Lilly’s substantial continuing obligations to comply with FDA requirements, Federal Health Care Program Requirements, and other federal statutes and regulations.<sup>25</sup> Further, the consent decree also provided that if the government unilaterally determines that other corrective actions are necessary to achieve compliance with the agreement, the government may order any additional action, the costs of which would be borne by the company.<sup>26</sup>

This provision effectively permitted the government to micromanage Eli Lilly’s compliance activities and potentially impose limitless burdens on the business.

These onerous and unprecedented terms were all the more questionable in light of the fact that the FDA later *approved* Evista for use in the treatment of breast cancer.<sup>27</sup> It is hard to discern a legitimate purpose behind the government’s actions against Eli Lilly where the purported misconduct—claiming that Evista was effective in the treatment of breast cancer—was later vindicated as scientifically sound by the FDA.

#### **ALLERGAN’S BOTOX PLEA AGREEMENT**

A second example of prosecutorial coercion in the pharmaceutical industry involves Allergan, Inc., the maker of Botox. In September 2010, Allergan resolved potential criminal and civil liability resulting from the company’s alleged off-label promotion of Botox. Allergan allegedly made it a top corporate priority to maximize the sales of Botox for headache, pain, spasticity, and juvenile cerebral palsy—uses not approved by the FDA.<sup>28</sup>

Similar to Eli Lilly, Allergan agreed to plead guilty to a criminal misdemeanor for misbranding Botox in violation of the FDCA. The plea agreement required the company to pay a criminal fine of \$375 million, which included forfeiting assets of \$25 million. To resolve outstanding and related civil claims that the company’s unlawful marketing practices caused false claims to be submitted to government healthcare programs in violation of the FDCA, Allergan agreed to pay an additional \$225 million to the federal government and

the states. The federal share amounted to \$210,250,000, and Allergan was required to pay up to \$14,750,000 to states that opted to participate in the agreement. Additionally, the civil settlement resolved three federal *qui tam* lawsuits pending in the Northern District of Georgia, and the five relators received \$37.8 million among themselves from the federal share of the settlement.<sup>29</sup>

“ *The most coercive portion of the agreement involved Allergan’s pending First Amendment lawsuit against the FDA, which the company had filed in October 2009, challenging the FDA’s policy on the distribution of truthful information about a product, for both on- and off-label uses. Before Allergan was permitted to even begin settlement negotiations with the DOJ, the Attorney General mandated that the company withdraw its potentially meritorious lawsuit.* ”

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Caroline Van Hove, an Allergan spokesperson, explained the basis for the company’s lawsuit: “With this lawsuit, we sought to gain better clarity regarding the rights of prescription drug companies to proactively share truthful scientific and medical information with the medical community, to assist physicians in evaluating the risks and benefits if they choose to use Botox off-label to treat certain forms of spasticity.”<sup>31</sup> Van Hove further stated that “[i]t’s disappointing that the court was not afforded an opportunity to hear and rule on these important First Amendment issues. The government made dismissal ... a mandatory condition of our global settlement.”<sup>32</sup>

Coercing Allergan into dismissing the case as a condition of settlement is itself anathema to the First Amendment’s free speech protection and will likely serve as a deterrent to other pharmaceutical companies interested in achieving a resolution of this key First Amendment issue. And shutting the courthouse doors to pharmaceutical companies seeking clarification of the applicable law undermines, rather than promotes, justice, turning a core government function on its head.

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### **VASCULAR SOLUTIONS’ BATTLE IN COURT**

The above examples are representative of what most pharmaceutical and medical device companies encounter when faced with government accusations of off-label promotion. However, the recent jury verdict in favor of Vascular Solutions, a Minnesota-based life sciences company, is at once both a welcome sign for the industry and strong evidence that in threatening prosecutions to obtain settlements, federal prosecutors are often overplaying their hand.

The DOJ’s Civil Division accused Vascular Solutions of marketing its Vari-Lase Short Kit to treat deep leg veins (perforator varicose veins), even though the FDA had only approved the device for treatment of more shallow veins.<sup>33</sup> While the company maintained that the FDA approved the drug for treatment of a general category of varicose veins, including perforator varicose veins, Vascular Solutions agreed in 2014 to a \$520,000 settlement of the civil claims, with no admission of liability.<sup>34</sup>

Despite this settlement, the DOJ’s Criminal Division subsequently brought a criminal indictment against the company several months later alleging off-label promotion of the kits and the sale of misbranded and adulterated devices. DOJ also asserted criminal conspiracy charges against

CEO Howard Root.<sup>35</sup> Maintaining their innocence, Vascular Solutions and Root took the case to trial.

The company sought dismissal of the indictment prior to trial, charging that the government had endeavored to distort the evidence by (a) warning witnesses to “fix” their testimony or face criminal prosecution; (b) telling a witness that he needed to make his testimony “consistent with” the testimony of others to avoid prosecution; (c) threatening to encourage Vascular Solutions to fire a witness whose testimony was “pissing off” the government; and (d) warning a witness that he was close to facing perjury charges.<sup>36</sup>

Although the federal court denied that motion, Senior District Court Judge Royce Lamberth<sup>37</sup> instructed the jury that it was “not a crime for a device company or its representative to give doctors wholly truthful and non-misleading information about the unapproved use of a device.”<sup>38</sup> Ultimately, the jury acquitted Vascular Solutions and Root of all charges, finding that there was no off-label promotion of the kit.

Root’s critique of the DOJ’s aggressive enforcement gambit is instructive: “These prosecutors could have gotten on the Metro and gone over to Maryland to talk to the FDA, instead of coming down here to San

Antonio for a four-week trial to find out that all varicose veins include perforator varicose veins,” referring to the plain language of the FDA’s approval of the drug. In a recent call with shareholders, Root stated that the company would be “pursuing administrative remedies within the Department of Justice and the Office of Inspector General in an attempt to prevent what happened to us from happening to others at the hands of these prosecutors.”<sup>39</sup>

To be sure, the court’s jury instruction is groundbreaking and will be a critical consideration by companies defending against overzealous off-label enforcement. But equally profound was Vascular Solutions’ decision to take the case to trial rather than succumb to the pressure of negotiating yet another settlement. Former U.S. Attorney John Richter stated that this was the only case of which he was aware in which a publicly-traded medical device company ran the risk of getting indicted, let alone going to trial.

Richter emphasized the unprecedented and risky nature of resisting the pressure to settle criminal charges, regardless of their merit.<sup>40</sup> He also noted the “tremendous leverage” the government has in exacting “extraordinarily large settlements” from pharmaceutical and medical device companies by pursuing off-label theories, noting that the “risk of exclusion for most companies is just too high to bear.”<sup>41</sup> Such “tremendous leverage,” combined with the fact that most settlements described above are not subject to review by a court, often yields “results that do not completely reflect the actual merits.”<sup>42</sup>

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Although Vascular Solutions was ultimately vindicated at trial, the company was forced to spend \$25 million defending itself against unmeritorious claims, illustrating the inherent cost of enforcement abuses, regardless of the outcome.<sup>43</sup> Additionally, “being under investigation, even if innocent, is a tremendous drag on the productivity of a publicly traded company, causing harm to reputation as a consequence.”<sup>44</sup> As Richter aptly put it, “[a]t the end of the day, prosecutors always hold tremendous power.”<sup>45</sup>

## State AGs Acting as a “Mini-FDA”

Another troubling development in government enforcement is the increasing frequency with which state attorneys general (AGs) are requiring companies to



abide by expansive terms and practices as a condition of settlement—dictates that go above and beyond the federal regulations and statutes to which these companies are already subject. In such cases, state AGs essentially act as “mini-regulators,” even though they typically lack any relevant expertise regarding the subject matter into which they are injecting themselves, resulting in misguided decisions and inconsistent standards.

In addition, superimposing additional regulatory requirements under “50 States’ tort regimes”<sup>46</sup> hamstrings the federal agency already tasked with tightly regulating the conduct at issue and

conflicts with the important objectives served by the discretion vested in it to enforce its own regulations.<sup>47</sup> Nowhere is this trend more palpable than in the prescription drug context—especially in the case of settlements based on off-label promotion—where state AGs are imposing requirements on pharmaceutical companies’ labeling and promotion efforts, which are already subject to the FDA’s comprehensive regulatory scheme.

Where Congress has already created a comprehensive, sophisticated regulatory scheme, it makes little sense for states to duplicate those efforts by transforming their law departments into mini-FDAs. After all, it would be virtually impossible for a business to simultaneously comply with the federal regulatory scheme and disparate requirements imposed by 50 state mini-FDAs. Even if it were somehow possible to comply with differing regulatory requirements, it would be cost prohibitive, likely driving out businesses from the national marketplace. Put simply, imposing these burdensome obligations on companies, on top of the statutory scheme provided by federal law (such as the FDCA), intrudes on the regulatory power granted to the federal agencies that are actually experts in their fields, and creates another layer of complicated requirements for companies to navigate in their day-to-day operations.

Given the patchwork of obligations a company may face following the resolution of an investigation or litigation, the safest option for a company is often to adhere to the most restrictive requirements in an attempt to avoid further conflict. But forcing companies to operate at such highly restricted levels is not necessarily

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in the best interests of society; in fact, it often results in wasting resources on navigating the regulatory patchwork rather than investing in the ordinary business of the company. Indeed, in the case of pharmaceutical products,

[t]he cost for producing and marketing [such] products to account for the peculiar requirement in [different] jurisdiction[s] ... increase[s], which ... raise[s] the price of the drugs for consumers or [is] subtracted from research and development budgets, thereby slowing the development of beneficial pharmaceutical products.<sup>48</sup>

### **OREGON AG'S CELEBREX AND BEXTRA SETTLEMENT**

In 2003, the Oregon AG instituted a multi-state investigation into Pfizer Inc. and Pharmacia Corporation (subsequently purchased by Pfizer) to determine whether the companies misrepresented that Celebrex, and later Bextra, were safer and more effective than traditional nonsteroidal anti-inflammatory drugs (NSAIDs).<sup>49</sup> The investigation focused on marketing of the drugs for off-label purposes not approved by the FDA.<sup>50</sup> In 2004, Oregon Senior Assistant Attorney General David Hart notified Pfizer that the Oregon AG intended to issue a civil investigative demand against the company. However, the Oregon Department of Justice (Oregon DOJ) agreed not to formally issue the investigative demand on the condition that Pfizer agree to enter into settlement negotiations and produce certain documents.<sup>51</sup>

Three years later, in October 2008, the Oregon DOJ ultimately sued Pfizer, and on the same day, Pfizer entered into a

stipulated judgment for \$60 million with Oregon, the District of Columbia, and 32 other states involved in the investigation. The judgment stated that Pfizer had entered into a stipulated judgment solely for the purpose of settling and that nothing in the judgment constituted an admission or concession of unlawful activity.<sup>52</sup>

Central to the settlement were far-reaching injunctive terms that addressed not just Celebrex and Bextra, the focus of the investigation, but more broadly applied to all Pfizer prescription drugs and biological products. Included in the judgment were provisions to prevent “ghost writing” of articles and studies, using patient testimonials to misrepresent a drug’s efficacy, using “mentorships” to pay physicians for time spent with Pfizer sales reps, and using sales personnel to make grant decisions that are supposedly unrelated to promotion and marketing, among other things.<sup>53</sup> Lastly, the judgment included a general proscription against “deceptive and misleading advertising and promotion of any Pfizer drug” and required Pfizer to register all clinical trials and post-clinical-trial results and ensure that subjects in Pfizer-sponsored clinical trials give adequate informed consent.<sup>54</sup>

These provisions imposed on Pfizer constitute what is effectively a competing set of regulations in the same areas regulated by the FDA: pre- and post-sale testing protocols, labeling/product usages, relationships with prescribing physicians, and consumer advertising. The FDA has already adopted regulations, applicable nationwide, that govern the development and testing of new products, establish



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procedures for obtaining pre-sale approval for any new product, determine the content and form of product labeling (including specifications of appropriate uses and warnings about potential risks), regulate the form and content of communications with potential prescribing physicians, and regulate the form and content of advertising directly to consumers. The states' settlement terms do not apply to any other company.

Such provisions may subject a company to state-imposed regulations that its competitors need not follow and that touch on areas within the unique province and expertise of the FDA. As one state's supreme court previously recognized, "Congress has enacted a comprehensive regulatory scheme, implemented by the FDA, which is meant to control the design, implementation, and marketing of prescription drugs, including both criminal and civil penalties for manufacturers that violate these regulations."<sup>55</sup> Agreements like the one between Pfizer and Oregon will disturb that important regulatory scheme and undermine the primacy of the FDA with respect to the marketing and sale of pharmaceutical drugs.

There are other examples of state AGs acting outside their expertise to impose burdensome requirements on pharmaceutical companies.

#### **ELI LILLY'S ZYPREXA SETTLEMENT**

Eli Lilly reached a \$62 million settlement with 33 state AGs related to its allegedly improper marketing of the antipsychotic drug Zyprexa. The AGs alleged that Eli Lilly engaged in unfair and deceptive practices when it marketed Zyprexa for off-label uses. Under the settlement, which has a six-year period, Eli Lilly is prohibited from promoting Zyprexa for off-label uses; must clearly indicate the FDA's approved uses for Zyprexa in any marketing promotions; may not use grants or continuing medical education activities as a means of promoting Zyprexa; and must disclose payments made to medical providers who are promotional speakers or consultants for Eli Lilly.<sup>56</sup> Following its settlement of the state consumer protection lawsuits, Eli Lilly also agreed to pay \$1.415 billion in a global resolution with the DOJ to resolve criminal and civil allegations, which included a plea agreement and entry into a five-year corporate integrity agreement with the Office of Inspector General.<sup>57</sup>

## MERCK SETTLES VIOXX MARKETING ALLEGATIONS

Merck agreed to pay \$58 million to settle allegations that the company downplayed health risks related to its pain-relief drug Vioxx in consumer advertisements. The settlement also included several injunctive elements, including: requiring Merck to obtain FDA approval before running television advertisements for new pain medications; prohibiting Merck from “ghostwriting” articles and studies for publication; requiring Merck to disclose conflicts of interest when Merck promotional speakers make presentations at supposedly independent continuing medical education programs; and requiring Merck to submit clinical trial results of

FDA-approved Merck products to the National Library of Medicine.<sup>58</sup> More than three years later, Merck entered into a \$950 million settlement with the DOJ to resolve criminal and civil charges related to its promotion and marketing of Vioxx. The settlement also included entry into an expansive corporate integrity agreement.<sup>59</sup>

Determining the appropriateness of the broad provisions outlined above is outside the expertise of state AGs, “whose staff and hired experts cannot approach the breadth and depth of the FDA’s technical expertise.”<sup>60</sup> As such, the question of whether these additional (and costly) steps are necessary is best left to the FDA.

## Expansive Legal Theories

Prosecutorial overreach can also be seen in cases where enforcement actions are based on novel or expansive interpretations of vague laws. Bending the law to support charges against companies and their representatives based on conduct not clearly prohibited or previously prosecuted under the law turns prosecutorial discretion into prosecutorial abuse. After all, “individuals and businesses cannot provide input into these [new theories], do not have notice of [them], and cannot shape their behavior to comply with the new [theories] until it is too late.”<sup>61</sup> It also gives the prosecutor an unfair advantage in obtaining settlement with companies eager to avoid the uncertainty of litigation over untested claims. Settlement in these cases is often appealing for the enforcement agencies, as it precludes the prosecution from actually having to prove the viability of their theories in court.

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## BAYER'S VICTORY OVER THE FTC

A clear-cut example of this kind of prosecutorial overreach was the Federal Trade Commission's (FTC) lawsuit against Bayer regarding its Phillips Colon Health (PCH) probiotics. The gravamen of the lawsuit was that the pharmaceutical company violated a prior settlement agreement by falsely advertising the product.

The allegedly contravened consent decree was entered into in 2007, after the U.S. filed a complaint against Bayer alleging that the company had violated a 1991 FTC administrative order to cease and desist certain advertising practices with respect to particular vitamin and mineral supplements. The lawsuit was settled, and Bayer agreed to pay a \$3.2 million civil penalty and enter into an agreement requiring, among other things, that Bayer rely upon "competent and reliable scientific evidence to support" representations about their supplements.<sup>62</sup>

In 2011, the FTC began investigating Bayer's compliance with this order, questioning whether Bayer possessed sufficient support for their marketing of PCH.<sup>63</sup> Bayer cooperated, producing nearly 100 scientific articles supporting its advertising claims. Nevertheless, in September 2014, the FTC filed a contempt motion seeking sizable penalties, including a \$25,000 per day fine, a recall of products containing the allegedly unsubstantiated claims, as well as compensatory damages.<sup>64</sup>

The FTC alleged that Bayer's claims regarding PCH were not supported by "competent and reliable scientific evidence" and that Bayer made

*“Rejecting the FTC’s unprecedented theory, Judge Jose Linares ruled that ‘[t]he government cannot seek contempt on the basis of a lone expert who proposes a standard that was not disclosed to industry until the day the government filed its contempt motion.’”*

unapproved implied disease claims—a standard that was nowhere to be found in either the 2007 agreement or agency precedents or regulations. The FTC presented the opinions of a single expert claiming that "competent and reliable scientific evidence" required certain human clinical trials, a novel theory dismissed by the U.S. District Court of New Jersey.<sup>65</sup>

Rejecting the FTC's unprecedented theory, Judge Jose Linares ruled that "[t]he government cannot seek contempt on the basis of a lone expert who proposes a standard that was not disclosed to industry until the day the government filed its contempt motion."<sup>66</sup> Counsel for the government even admitted during trial that "you have to go outside of the four corners of the consent decree" for its argument to

have any validity.<sup>67</sup> Further, the court found no evidence that Bayer had made implied claims of any kind, let alone unapproved disease claims, finding “[t]he suggestion of ‘implied’ disease claims ... is contrary to the record and rests solely on arguments of counsel.” Moreover, as the court explained, the FTC’s own guidance on the issue specifically refuted the standard it was seeking to impose in this suit,<sup>68</sup> illustrating the extent of the government’s overreach and abuse, as well as the inclination of government to subject companies to inconsistent standards.

In short, “Bayer faithfully followed the law, including the FTC’s own guidance. The government was simply trying to impose a novel and unlawful standard, and the court properly rejected this overreach, denying the government’s motion in its entirety.”<sup>69</sup> While the FTC’s novel theory was ultimately rejected in court, it came at a tremendous cost to Bayer after spending considerable resources to defend itself against the government’s allegations and in a putative class action asserting the same allegations.

### **DEATH MASTER FILES/UNCLAIMED PROPERTY LAWS: METLIFE SETTLEMENT**

A second illustration of the expansive legal theories trend is the recent practice by some administrators of state unclaimed property laws to pursue insurance companies that fail to turn over unclaimed insurance benefits after beneficiaries die—even though state insurance laws have generally provided that insurance benefits are not “unclaimed” until the policies mature, which may not occur until sometime after a beneficiary’s death.

Based on aggressive readings of unclaimed property laws, state officials have extracted substantial settlements from insurers by alleging that their failure to determine proactively which beneficiaries might have died and to turn over their assets to the state in short order violates state law.

In April 2012, for example, life insurance company MetLife agreed to pay approximately \$500 million in a multi-state settlement to resolve accusations by state insurance regulators and controllers that the company had delayed or withheld life insurance payments from its policyholders.<sup>70</sup> The settlement proceeds not claimed by beneficiaries of policyholders were retained by the state as unclaimed property. The settlement resulted in part from a multiyear audit of MetLife’s insurance practices conducted by California State Controller John Chiang as part of a joint investigation with California Insurance Commissioner David Jones.<sup>71</sup>

As part of the settlement, the company stated that “MetLife agrees that periodic matching of administrative records against available external sources such as the Social Security Death Master File [(DMF)] is a best practice and the company is implementing a monthly matching process.”<sup>72</sup> Notably, the company said that it had paid out about \$12 billion in life insurance claims the previous year, with 99 percent of claims submitted by beneficiaries, and that “[p]olicyholder deaths that don’t involve a claim,” that is, those that would involve matching administrative records against the DMF “are a ‘small proportion’ of the total.”<sup>73</sup>

*“ The increasing number of regulatory inquiries, audits, settlements, and civil lawsuits concerning the enforcement of state unclaimed property laws and use of the DMF is a direct result of ‘cash-strapped states looking for new revenue streams and state financial officers using private contingency-fee firms to audit insurers for allegedly past due unclaimed property.’ ”*

Controller Chiang had conducted an audit of 21 other insurance companies in prior years, investigating whether the companies were in compliance with a California law requiring businesses to send lost or abandoned financial accounts to the state after three years.<sup>74</sup> The audit found that insurance companies did not routinely cross-check the owners of inactive accounts with the DMF.

This audit resulted in a multi-million dollar settlement with John Hancock (Hancock) in April 2011, under which the company agreed to pay out more than \$20 million in death benefits and to implement new processes to manage abandoned property.<sup>75</sup> According to a report in *USA Today*, the company claimed that the processes required by the settlement were “well beyond those required of insurers by law or regulation.”<sup>76</sup> Hancock insisted that it did nothing wrong and that “Chiang’s characterization of its behavior is unfair and inaccurate,” stating that “Hancock is outraged by the unfounded allegations and characterizations.”<sup>77</sup>

By all reasonable measures, Hancock’s characterization was right on the mark. After all, state unclaimed property laws have generally recognized that, based on state insurance code terms, life insurance is not considered “unclaimed” until maturity or, in the absence of a claim, when the insured reaches his or her limiting age.<sup>78</sup> In recent years, however, state unclaimed property administrators have begun asserting that life insurance proceeds are due and payable upon the death of the insured, regardless of whether there is a claim from a beneficiary, and that insurance companies are obligated to utilize the DMF to confirm whether any of their policyholders have passed away.<sup>79</sup> The increasing number of regulatory inquiries, audits, settlements, and civil lawsuits concerning the enforcement of state unclaimed property laws and use of the DMF is a direct result of “cash-strapped states looking for new revenue streams and state financial officers using private contingency-fee firms to audit insurers for allegedly past due unclaimed property.”<sup>80</sup>



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*“Injecting a profit motive into law enforcement carries a significant risk of abuse, and insurance audits have become increasingly aggressive and overreaching.”*

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When states use auditors who are paid on a contingency fee basis, it increases opportunities for coercion and overreach, as auditors are paid based on a proportion of the “unclaimed property” identified. Indeed, it is clear that “[s]tates benefit from enforcing unclaimed property laws because the funds are held indefinitely, acting as an interest-free loan for the state, and many owners never come forward to claim the funds. It follows that economically strained states strongly enforce these laws and may improperly treat them as a revenue source rather than as a property right.”<sup>81</sup> Injecting a profit motive into law enforcement carries a significant risk of abuse, and insurance audits have become increasingly aggressive and overreaching.

Further complicating the legal and regulatory landscape in which insurance companies operate, several court decisions have rejected the position of state unclaimed property administrators and regulators, holding that, in the absence of legislation to the contrary, insurers are not required to use external databases such as the DMF

to administer claims.<sup>82</sup> These “[c]ourts are looking to statutory and contractual language, and are rejecting arguments asserted by states in attempting to create new duties for insurance companies that are not based on legislative enactments.”<sup>83</sup>

Nonetheless, neither judicial decisions nor the plain meaning of legislative enactments have quelled state efforts to expand insurance law by executive fiat and settlements like those entered into by MetLife and Hancock. The persisting ambiguity in the law will likely continue to be exploited by officials in states that have not squarely resolved the issue in favor of insurers, giving those officials strong leverage in forcing settlements regardless of the merits of their position under state law.

#### **CRIMINALIZING THE GIVING OF LEGAL ADVICE: PROSECUTION OF GSK IN-HOUSE COUNSEL**

The DOJ’s failed prosecution of former GlaxoSmithKline (GSK) in-house counsel Lauren Stevens represents another attempt at expanding the zone of government enforcement.<sup>84</sup>

On November 8, 2010, a federal grand jury in the District of Maryland indicted Stevens on one count of obstructing an official proceeding, one count of falsification and concealment of documents, and four counts of making false statements in connection with a series of responses to the FDA’s request that GSK *voluntarily* provide information related to potential off-label promotion of Wellbutrin.<sup>85</sup> These charges subjected Stevens, a retired vice president and former in-house attorney for GSK, to a maximum of 60 years in federal prison.<sup>86</sup>

The DOJ's investigation began in 2002, almost a decade before Stevens was indicted, when the DOJ requested that GSK send "copies of all slides ... and other materials presented or distributed at any program or activity related to Wellbutrin," in addition to related compensation information.<sup>87</sup> Stevens and a team of outside counsel and GSK employees conducted an extensive internal investigation, including a review of physician slide decks used by doctors, some of which discussed off-label uses for Wellbutrin. Stevens and her team sent follow-up letters to the doctors stating that "[a]ny affirmative presentation in a GSK-sponsored non-independent program" relating to unapproved usage of Wellbutrin was inconsistent with the physician's contract with GSK and FDA requirements.<sup>88</sup>

Following this collaborative, internal investigation, Stevens coordinated the GSK team's response to the FDA and submitted letters to the FDA representing that GSK had not "developed or maintained promotional plans to promote Wellbutrin for weight loss," among other statements.<sup>89</sup> The government ultimately charged that these statements were all criminally false statements. While Stevens signed all of the letters to the FDA, "the first drafts were done by outside counsel, and the final submissions were the yield of a collaborative process that included two other in-house lawyers and GSK's outside counsel."<sup>90</sup>

As part of its investigation, the government obtained an order that GSK disclose attorney-client privileged documents to the government under the crime fraud exception to the privilege.<sup>91</sup> While the first

indictment was ultimately dismissed on March 23, 2011, without prejudice, Stevens was indicted again based on the same charges.<sup>92</sup> Stevens advanced an "advice of counsel" defense, arguing that because she relied in good faith on the advice of outside counsel, she lacked the intent necessary to be found guilty of making false statements and obstructing justice.<sup>93</sup>

On May 10, 2011, U.S. District Judge Roger Titus dismissed the DOJ's indictment for the second time, noting that Stevens "should never have been prosecuted and that she should be permitted to resume her career."<sup>94</sup> In granting Stevens' Rule 29 Motion for Acquittal, Judge Titus was persuaded by Stevens' reliance on the advice of counsel; he noted that the documents revealed the "studied, thoughtful analysis of an extremely broad request from the [FDA] and an enormous effort to assemble information and respond on behalf of the client."<sup>95</sup> He further stated that "a lawyer should never fear prosecution because of advice that he or she has given to a client who consults

*“Notably, the prospect of holding individuals responsible for alleged corporate misdeeds under novel theories has only increased since the DOJ's failed attempt to impose liability on Stevens.”*



him or her” and that “there is an enormous potential for abuse in allowing prosecution of an attorney for the giving of legal advice.”<sup>96</sup>

Given the dismissal of the indictments and language of Judge Titus’s ruling, this aggressive enforcement action was largely considered a “blow to government efforts to pin blame for alleged corporate wrongdoing on individuals.”<sup>97</sup> In defense of the prosecution, however, Tony West, the assistant attorney general for the Civil Division, noted that “[w]here the facts and the law allow, the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations.”<sup>98</sup> Although Stevens was vindicated, the case underscores the potential risks of aggressive enforcement of companies and their in-house counsel based solely on the furnishing of legal advice with which the government disagrees.

Notably, the prospect of holding individuals responsible for alleged corporate misdeeds under novel theories has only increased since the DOJ’s failed attempt to impose liability on Stevens. Specifically, in a Memorandum dated September 9, 2015, from Deputy Attorney General Sally Quillian Yates to all DOJ attorneys (the Yates Memo), the DOJ announced an initiative to hold individuals responsible for corporate wrongdoing, both criminal and civil.<sup>99</sup> The Yates Memo is the culmination of a series of DOJ memoranda that began in 1999 with the Holder Memo, which pertained to bringing criminal charges against corporations.<sup>100</sup> The “most impactful aspect of the Yates Memo” is the requirement

“ *While it is too early to quantify the precise impact the Yates Memo will have on government enforcement, federal prosecutors now have an official policy statement encouraging them to hold individuals criminally and civilly liable for alleged corporate wrongdoing.* ”

that corporations provide to the DOJ “all relevant facts about the individuals involved in the corporate misconduct ... [t]o be eligible for *any* cooperation credit.”<sup>101</sup> Some of the most salient implications for corporations and their individual employees include the following:

First, [corporations] might choose not to cooperate at all under these circumstances, which could lead to enhanced penalties in the event of adverse findings. Second, the government might determine not to give corporations credit for cooperating, on the basis that the corporation did not go far enough .... The DOJ (or a corporation seeking credit, for that matter) could end up taking too expansive a view of

individual involvement in the context of cooperation credit, thereby needlessly putting individuals at risk of criminal or civil liability.<sup>102</sup>

At bottom, the Yates Memo will likely accelerate—rather than curb—enforcement abuses at the federal level. While it is too early to quantify the precise impact the Yates Memo will have on government enforcement, federal prosecutors now have an official policy statement encouraging them to hold individuals criminally and civilly liable for alleged corporate wrongdoing. Even if this new policy statement does not result in increased criminal prosecution of individual employees, “DOJ lawyers could take advantage of the leverage that potential individual liability creates to convince corporate decision-makers to agree to unduly large settlements on behalf of corporations.”<sup>103</sup>

#### **NOVEL THEORIES AND PUNISHMENT: OFF-LABEL “PROMOTION” OF EVISTA**

The investigation and charges brought against Eli Lilly for alleged off-label promotion of its osteoporosis drug Evista, described above, is a further example of the government’s expansive reading of the FDCA. Because the FDCA does not delineate specific activities that are considered “promotion” of a drug for a

particular purpose by a pharmaceutical company, determining whether a certain business practice may constitute illegal off-label “promotion” lies within the sole discretion of the prosecutor.

In the Evista case, the government brought charges against Eli Lilly for, among other things, “organizing a ‘market research summit’ during which Evista was discussed with physicians for unapproved uses,” and “[c]alculating the incremental new prescriptions for doctors who attended Evista advisory board meetings in 1998 ... By measuring and analyzing incremental new prescriptions for doctors who attended the advisory board meetings, Lilly was using this intervention as a tool to promote and sell Evista.”<sup>104</sup> This was the first case in which the DOJ characterized market research as a tool for off-label promotion—raising significant questions regarding whether Eli Lilly had fair notice of the government’s novel and expansive theory of liability.<sup>105</sup>

Notably, the theory of liability advanced by the government was not the only unprecedented aspect of the case. The consent decree entered into in the case contained a \$24 million equitable disgorgement order. This was the first time in the context of off-label marketing that the FDA had sought to divest a company

*“ The consent decree entered into in the case contained a \$24 million equitable disgorgement order. This was the first time in the context of off-label marketing that the FDA had sought to divest a company of its supposed profits from improper sale of the product at issue. ”*

of its supposed profits from improper sale of the product at issue.<sup>106</sup> The novel nature of the disgorgement order was especially problematic because it did not contain any detailed explanation of how the \$24 million figure even related to the company's profits from off-label sales of Evista during this time period.<sup>107</sup>

## CPSC Settlements: Arbitrary Enforcement

A final form of enforcement abuse is arbitrary and capricious prosecution, which threatens the due process rights of companies. As the U.S. Supreme Court has explained, due process requires that “regulated parties should know what is required of them so they may act accordingly” and that “*precision and guidance* are necessary so that those enforcing the law do not act in any arbitrary or discriminatory way.”<sup>108</sup> Unfortunately, certain government agencies are failing to heed these basic precepts, pressuring companies to agree to settlements involving exorbitant penalty amounts that are not tethered to any standards, and that are in some instances fundamentally inconsistent with penalty awards underlying prior settlements involving similar alleged misconduct. This dynamic is playing out with increasing frequency in the case of settlements foisted onto product companies by the Consumer Product Safety Commission (CPSC).

CPSC Chairman Elliot Kaye announced his intention to seek increased civil penalties for the failure to report potential defects following the passage of the Consumer Product Safety Improvement Act of 2008 (CPSA), which provided for a roughly ten-fold increase in the maximum penalties permitted under the act, on multiple occasions.<sup>109</sup> Most civil penalty investigations brought by the CPSC end in settlement, however, given the understandable preference of many companies for avoiding the associated negative press, high costs and uncertainty of litigation.<sup>110</sup> A troubling aspect of these settlements is that the CPSC provides little “meaningful context about the amount of the penalty given the circumstances of the case and the application of the [CPSA’s] Section 20(b) statutory factors.”<sup>111</sup>

Notably, the propriety of these settlements has been called into question by one of the CPSC’s own commissioners, Joseph Mohorovic, who went so far as to vote against the approval of a settlement with Office Depot over reports of malfunctioning office chairs because of the amount of the fine demanded (\$3.4 million) and the method by which the CPSC determined that figure.<sup>112</sup> As Commissioner Mohorovic explained, the “problem is that we as a Commission have given ... public servants—and our stakeholder community—too little guidance regarding our penalties.”<sup>113</sup> The CPSC’s “current and historic black box approach to civil penalty

“Notably, the propriety of these settlements has been called into question by one of the CPSC’s own commissioners, Joseph Mohorovic, who went so far as to vote against the approval of a settlement with Office Depot over reports of malfunctioning office chairs because of the amount of the fine demanded (\$3.4 million) and the method by which the CPSC determined that figure.”

settlements contributes to a perception of arbitrariness,”<sup>114</sup> making it difficult for businesses to learn from the experiences of other companies.<sup>115</sup>

An example involves Baja Inc. and its corporate affiliate, One World Technologies, which agreed to pay a \$4.3 million civil penalty in 2014 for failing to report alleged defects in models of their go-carts and minibikes.<sup>116</sup> Baja did not file its full report with the CPSC until June 2010. By that

time, according to the CPSC, the company had received several complaints of fires and stuck throttles. Baja redesigned the fuel line to fix the problem, but had not notified consumers or the CPSC of the changes. Federal law requires manufacturers, distributors, and retailers to report to the CPSC immediately (within 24 hours) after obtaining information “reasonably supporting the conclusion that a product contains a defect which could create a substantial product hazard, creates an unreasonable risk of serious injury or death, or fails to comply with any consumer product safety rule or any other rule, regulation, standard, or ban enforced by CPSC.”<sup>117</sup>

While the Baja penalty was the largest imposed to date for a reporting violation, the CPSC failed to provide any guidance on reporting when issuing its penalty assessment. Baja stated that it received four fire reports “out of over 250,000 units on the market,” noting that in three instances the cause of the incident could not be determined. Moreover, Baja claimed that the stuck throttles were not clearly caused by fuel line and cable positioning, but could have been due to other factors. CPSC and Baja did not disclose when Baja received these reports.<sup>118</sup> CPSC similarly did not disclose how the penalty was calculated, offering similarly situated companies zero guidance and fair notice as to what type of conduct would trigger the kind of penalty imposed in the Baja case.

# Opening the Floodgates: Pile-On Litigation and Parallel Enforcement

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The abuses and harms described in this section focus on the detrimental effects of cumulative enforcement actions—both simultaneous and successive—on companies that find themselves either at the bottom of an avalanche of enforcement actions (in the case of “swarm”<sup>119</sup> or “pile-on” enforcement), in the middle of an enforcement tug-of-war (in the case of parallel enforcement), or both. These types of actions drain companies of resources better spent elsewhere—for example, on research and development—and create uncertainty in the day-to-day operations of businesses.

## Bandwagon Litigants and Settlement Seekers

A single investigation or settlement, whether or not meritorious, has the potential to ignite a chain reaction of subsequent investigations and litigation by other government entities. Under a patchwork of inconsistent laws and regulations, this phenomenon is becoming an increasingly prevalent reality in our current legal landscape. It is not at all uncommon for the announcement of a single investigation by the DOJ to spur the filing of many more lawsuits and

investigations by up to 50 state AGs, state and federal regulators, counties and municipalities, international regulators, private class action attorneys, investors, and consumers. The ensuing patchwork of pile-on litigation effectively forces the target company to become embroiled in litigation and investigations indefinitely, depriving it of the benefits of finality—a highly valued concept in the legal world. This concept is also critically important to the business world, which is forced to navigate an unpredictable and costly maze of endless enforcement proceedings.

*“ [S]ubjecting companies to an onslaught of duplicative investigations and litigation based on conduct already corrected wastes money and serves no greater purpose for society. ”*

The abusive aspects of this pile-on litigation are also evidenced by the fact that federal and state government entities and private plaintiffs bringing later claims are often simply looking to ride the coattails of the initial investigation, without the intent or resources to diligently pursue their own investigation or litigation. The sheer volume of potential lawsuits and claims from other parties is often enough to force a company into settling subsequent claims as well, regardless of the merits of those individual claims.

In addition to costing companies large sums of money that bear no relationship to the merits of the underlying claims, these settlements also cause serious reputational harm to these businesses. This is especially so given the proclivity of some government entities to grandstand and publicize settlements as enforcement “wins,” regardless of a defendant’s motivation for settling.

Moreover, forcing a company to defend and address duplicative actions does not in any way benefit American consumers. This is particularly so because in many cases, at least where the federal government files the first action and obtains relief

through settlement or other means, it is unclear what remains for subsequent, follow-on actions by states or other parties to accomplish. After all, an initial settlement with the federal government will typically include expansive injunctive provisions requiring the company to remediate its internal policies and cease the purported misconduct. The settlement may also include substantial penalties intended to reflect the federal government’s assessment of the compensation owed or the fine needed to address the conduct at issue.

In many cases, the only apparent purpose of follow-on enforcement proceedings is to allow “the state or private lawyers [to] secure millions of dollars in additional fines and attorney fees,” a purpose that can work to the detriment of virtually all other parties when such efforts “lead to contrary and confusing results that do little to promote consumer welfare.”<sup>120</sup> Ultimately, this seemingly endless cycle of pile-on litigation actually harms society by denying it the fruits of company investments in research, development, and services, which are reduced in order to fund the defense against the duplicative litigation.



## **DISCOVER'S PAYMENT PROTECTION PLAN LITIGATION**

A prime example of the pile-on phenomenon is the litigation challenging practices allegedly used by Discover Financial Services in marketing its credit card payment protection plans (e.g., registering consumers without consent, overcharges). The controversy commenced in 2010 with the filing of eight separate class action lawsuits on behalf of all consumers who participated in the programs at issue.<sup>121</sup> Discover negotiated a \$214 million global settlement of those cases that offered compensation to all allegedly aggrieved consumers nationwide. That settlement was approved by an Illinois federal district court in May 2012, but that was hardly the end of the story.

Even though those class action settlements compensated consumers for their alleged losses, attorneys general of several states (including West Virginia, Hawaii, Minnesota, and Missouri) joined the fray, filing state consumer protection statute actions seeking to impose penalties on Discover based on the same allegations.<sup>122</sup> Additionally, the Consumer Financial Protection Bureau (CFPB) and the Federal Deposit Insurance Corporation (FDIC) brought a joint enforcement action against Discover. That effort was resolved in September 2012, on the heels of the class action settlement, with Discover agreeing to refund \$200 million to 3.5 million customers who purchased credit card products and to pay \$14 million in civil fines to the CFPB and the FDIC.<sup>123</sup>

If that weren't enough, in the wake of the CFPB/FDIC enforcement action, a number of purported shareholders brought derivative actions against Discover, as well as the board of directors and certain current and former officers, for alleged breach of fiduciary duty, corporate waste, and unjust enrichment arising out of the same alleged violations of the law in connection with the marketing and sale of its payment protection plans.<sup>124</sup> In September 2012, the actions filed in the U.S. District Court for the Northern District of Illinois were consolidated and ultimately dismissed with prejudice on March 17, 2016.<sup>125</sup> A shareholder derivative suit brought by Steamfitters Local 449 Pension Fund containing substantially the same allegations related to Discover's marketing and sale of payment protection plans remains stayed in Illinois Circuit Court.<sup>126</sup>

## **JPMORGAN'S \$13 BILLION-DOLLAR SETTLEMENT WITH THE DOJ**

Another example of pile-on enforcement is the DOJ's unprecedented \$13 billion settlement with JPMorgan to "resolve federal and state civil claims arising out of the packaging, marketing, sale and issuance of residential mortgage-backed securities (RMBS) by JPMorgan, Bear Stearns, and Washington Mutual prior to Jan. 1, 2009."<sup>127</sup> As part of its negotiations with the federal government, JPMorgan agreed to settle claims not only by the DOJ, but also by several federal agencies and states, including the FDIC, the National Credit Union Administration (NCUA), the Federal Housing Finance Agency, and the states of California, Delaware, Illinois, Massachusetts, and New York.<sup>128</sup> While



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some of these states and other entities had opened official investigations against JPMorgan at the time, the sheer magnitude of the settlement made it easier for states uninterested or unable to invest their own time and resources into conducting a full investigation into JPMorgan’s actions to get a spot at the settlement table.

At first blush, providing states that lacked the resources to conduct their own full investigations an opportunity to participate in a settlement based on alleged conduct that arguably affected their citizens might seem consistent with the public interest. But it also likely had the pernicious effect of inflating the size of the unprecedented settlement and precipitated the filing of pile-on litigation by other government entities

and private plaintiffs. Moreover, while JPMorgan negotiated the global amount of the settlement with the DOJ, JPMorgan had no role in dividing the settlement proceeds proportionally among all entities involved.

At the time, the \$13 billion deal with the government was “the largest settlement with a single entity in American history,” and it received enormous attention from media outlets around the country.<sup>129</sup> A high degree of media attention was exactly what U.S. Attorney General Eric Holder had set to achieve: “The size and scope of this resolution should send a clear signal that the Justice Department’s financial fraud investigations are far from over.”<sup>130</sup> But the JPMorgan settlement did more than serve as a cautionary tale for other financial institutions. The extravagant settlement and publicity continued to prompt litigation by other entities and individuals, including investors and state governments that had previously sat on the sidelines of the earlier resolution led by the federal government. Having seen the initial efforts pay off, a fresh wave of new litigants jumped into the fray, eager to capitalize on JPMorgan’s apparent vulnerabilities.

One of these suits, brought by the Fort Worth Employees’ Retirement Fund and other investors, settled for \$388 million.<sup>131</sup> Another settlement was reached in early January 2016, under which JPMorgan agreed to pay \$48 million to settle remaining issues arising out of its handling of mortgage servicing accounts after the 2008 financial crisis.<sup>132</sup> These types of suits continue to be brought, even though much

of the alleged wrongdoing occurred many years ago and has since ceased by virtue of the \$13 billion settlement with the federal government in 2013.<sup>133</sup>

### **GOLDMAN SACHS' RECENT \$5.1 BILLION SETTLEMENT WITH THE RMBS WORKING GROUP**

Goldman Sachs recently announced a settlement of \$5.1 billion to resolve allegations that it failed to properly vet mortgage-backed securities. The settlement resolves an ongoing investigation of the DOJ-led RMBS Working Group of the U.S. Financial Fraud Enforcement Task Force (the Working Group).<sup>134</sup> In addition to resolving claims with the DOJ, the deal also resolved actual and potential claims by a number of other state and federal authorities, including the attorneys general of New York, California, and Illinois, as well as claims by the NCUA and the Federal Home Loan Banks of Chicago and Seattle.<sup>135</sup>

The \$5.1 billion settlement is only one of many RMBS settlements that Goldman has been involved in regarding complaints stemming from its actions in the years leading up to the financial crisis. As a result of these settlements, Goldman continues to pay billions of dollars to resolve similar legal and regulatory complaints—an illustration of the interminable nature of the pile-on effect.

The start of this pile-on litigation was a 2010 civil lawsuit filed by the Securities and Exchange Commission (SEC) against Goldman and one of its employees; the suit alleged that the firm had defrauded investors in the sale of securities tied to subprime mortgages. The SEC's case not

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only “tarnished the gilded reputation of Wall Street’s top firm” but also “exposed the company to a series of new legal attacks across a number of fronts.”<sup>136</sup> The lawsuit was particularly surprising because the company had been cooperating with the SEC’s probe of the activities underlying the suit.<sup>137</sup> Goldman ultimately paid \$550 million to the SEC to settle the charges, the “largest penalty ever assessed against a financial services firm in the history of the SEC.”<sup>138</sup> Goldman neither admitted to nor denied the allegations in the underlying suit.

In May 2010, following the filing of the SEC's civil case, federal prosecutors opened a criminal investigation into Goldman and its employees to determine whether the company had committed securities fraud in its mortgage trading operations. German and British officials, including U.K. Prime Minister Gordon Brown, subsequently demanded investigations into Goldman's dealings, and state law enforcement officials announced that they were considering formal state investigations as a result of the SEC's allegations.<sup>139</sup> The DOJ later announced in 2012 that it would not pursue criminal charges against Goldman, ultimately concluding that "the burden of proof to bring a criminal case could not be met based on the law and facts as they exist at this time."<sup>140</sup> And in August 2014, Goldman also paid over \$3 billion to the Federal Housing Finance Agency in order to settle RMBS claims with Fannie Mae and Freddie Mac.<sup>141</sup>

Similar pile-on litigation has hit various large banks, including Barclays PLC, Credit Suisse Group AG, Deutsche Bank AG, HSBC Holdings PLC, Royal Bank of Scotland Group PLC, UBS AG, and Wells Fargo & Co.<sup>142</sup> Following Goldman's settlement, U.S. Attorney Benjamin B. Wagner of the Eastern District of California announced that these results "continue to send a message to Wall Street that [the Working Group] remain[s] committed to pursuing those responsible for the financial crisis."<sup>143</sup> While the government views the Working Group's investigations as a way to "hold bad actors in the market accountable,"<sup>144</sup> the banks involved "viewed them as punishment for activities that they have since stopped and as a distraction from their efforts to ramp up lending and help aid economic growth."<sup>145</sup>

### **WELLS FARGO'S RECENT \$1.2 BILLION SETTLEMENT**

Similar to the pile-on mortgage-related enforcement litigation described above, Wells Fargo recently agreed to pay \$1.2 billion to settle claims brought against it and one of its executives related to its sale of residential loans between 2001 and 2008. The agreement resolved a civil lawsuit filed in the Southern District of New York in 2012. Wells Fargo initially contested the allegations in the lawsuit, arguing as one of its key defenses that a \$25 billion federal-state mortgage settlement reached earlier in 2012 with other top banks had already resolved some of the company's liability.<sup>146</sup>

*“ Concerned about the uncertain and costly nature of pile-on litigation, however, Wells Fargo ultimately paid additional money to settle the claims from the civil lawsuit on top of a number of additional related actions, resulting in the largest recovery for loan origination violations in the Federal Housing Administration’s (FHA) history. ”*

Concerned about the uncertain and costly nature of pile-on litigation, however, Wells Fargo ultimately paid additional money to settle the claims from the civil lawsuit on top of a number of additional related actions, resulting in the largest recovery for loan origination violations in the Federal Housing Administration's (FHA) history.<sup>147</sup> In addition to resolving claims from the civil lawsuit, the settlement also resolved an investigation conducted by the U.S. Attorney's Office for the Southern District of New York regarding Wells Fargo's FHA origination and underwriting practices subsequent to the claims in the lawsuit, and an investigation conducted by the U.S. Attorney's Office for the Northern District of California related to the practices of American Mortgage Network, LLC, a mortgage lender that Wells Fargo acquired in 2009.<sup>148</sup>

It is clear from these recent settlements that even today, the pile-on enforcement that has unfolded in the wake of the federal government's unprecedented settlement with JPMorgan in 2013 does not appear to have any end in sight; in fact, it will likely continue to generate "punishments" in the financial services industry that are highly tangential to the alleged wrongdoing.

## Parallel Enforcement: Inconsistent Standards

In addition to contending with a multiplicity of successive lawsuits and investigations following an initial litigation, companies also face the threat of parallel enforcement of the same alleged conduct by multiple entities simultaneously. This problem

is particularly applicable to companies operating in highly regulated industries, such as healthcare and financial services, which experience this threat acutely. Such companies deal with regulatory and administrative agencies on a daily basis—a practice that establishes a course of dealing built on trust and mutual understanding. That dynamic is jeopardized when the DOJ or a state government seeks to inject itself into the regulatory equation. Simultaneous intervention by these outside players often subjects American businesses to inconsistent standards and undermines their ability to rely on guidance provided by agencies with whom they regularly work.

JPMorgan's experience again provides an example. In February 2014, the DOJ announced that JPMorgan would pay \$614 million for "knowingly originating and underwriting non-compliant mortgage loans submitted for insurance coverage and guarantees by the Department of Housing and Urban Development's (HUD)[,] Federal Housing Administration (FHA)[,] and the Department of Veteran Affairs (VA)" in violation of the False Claims Act.<sup>149</sup>

As part of the settlement, JPMorgan admitted that it had "approved thousands of FHA loans and hundreds of VA loans that were not eligible for FHA or VA insurance because they did not meet applicable agency underwriting requirements."<sup>150</sup> JPMorgan further acknowledged that it had "failed to inform the FHA and VA when its own internal reviews discovered more than 500 defective loans that never should have been submitted for FHA or VA insurance."<sup>151</sup>

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*“ JPMorgan and HUD had proceeded under a different understanding than the one imposed by the DOJ when it swooped in to investigate the hyper-technical violations. This uncertainty is common in the financial services area because the ‘rules that govern when and why the FHA or the Department of Justice take action are not necessarily clear.’ ”*

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Prior to the DOJ’s involvement, however, JPMorgan was already involved in negotiations to resolve the issue with HUD, the agency with which Congress vested responsibility for enforcement of the regulatory regime. In the course of those dealings, JPMorgan and HUD had proceeded under a different understanding than the one imposed by the DOJ when it swooped in to investigate the hyper-technical violations. This uncertainty is common in the financial services area because the “rules that govern when and why the FHA or the Department of Justice

take action are not necessarily clear.”<sup>152</sup> For instance, if the FHA determines that a lender made mistakes in issuing certain loans or failed to meet the agency’s quality standards, the FHA can take recourse by forcing the lender to indemnify the agency; if the DOJ finds that the mistakes violate the law, it can pile-on by taking legal action, often resulting in large settlements, as was the case with JPMorgan.<sup>153</sup>

The DOJ’s interference with JPMorgan’s ongoing business with HUD nullified the significant investment in time and resources the company had made in resolving the issue, leading JPMorgan CEO Jamie Dimon to comment in July 2014 that his bank may even stop doing business with the FHA.<sup>154</sup> Dimon criticized the government for taking JPMorgan to court “over what should have been nothing more than a commercial dispute,” and went on to lament that he was “thoroughly, thoroughly confused” about how the government had treated JPMorgan.<sup>155</sup> “There should be a commercial resolution of this dispute, where you don’t have triple damages if something goes wrong,” Dimon said.<sup>156</sup>



The parallel enforcement described above not only adversely impacted JPMorgan, but also ended up harming consumers, as JPMorgan reduced the number of FHA loans to American consumers. Hamstrung by the DOJ's aggressive intervention and interpretation of the controlling law, JPMorgan reduced its FHA business by 74 percent.<sup>157</sup> JPMorgan's reduction in FHA business represents money that could have gone to consumers seeking homes, but instead had to be held back out of a concern by a major financial services company that further investment would

leave it exposed under the DOJ's view of the law—both to future triple-damages claims by the DOJ and to pile-on claims brought by states or other potential litigants. Notably, JPMorgan is not the only large bank to curtail its FHA business. Many of the largest U.S. home lenders are cutting back on FHA mortgages out of concerns that they will be penalized for the same kind of conduct underlying the JPMorgan settlement.<sup>158</sup> The result is that “[h]ome loans to lower-income Americans are dwindling”—certainly not a positive development for the American consumer.

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# Excessive Punishment

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Another rampant area of enforcement abuse involves excessive punishment—that is, where the severity of the sanction, fine, or obligations imposed to resolve an enforcement action is disproportionate to the severity of the alleged wrongdoing. The U.S. Supreme Court “has explicitly recognized proportionality in this context as essential to protect individual rights—namely, the property interest identified in the Due Process Clause of the Fourteenth Amendment.”<sup>159</sup>

The U.S. Supreme Court has also made clear that the Eighth Amendment’s Excessive Fines Clause prohibits “grossly disproportionate” civil penalties.<sup>160</sup> In reviewing civil fines for excessiveness, the U.S. Supreme Court “ha[s] focused on the same general criteria” that it applies when reviewing the propriety of punitive damages awards under the Due Process Clause of the Fourteenth Amendment: “the degree of the defendant’s reprehensibility or culpability, the relationship between the penalty and the harm to the victim caused by the defendant’s actions, and

the sanctions imposed in other cases for comparable misconduct.”<sup>161</sup> In recent years, state AGs have either overlooked or, worse, intentionally disregarded these bedrock constitutional principles in their crusade to deliver money to their states and further their political agendas.

Among the sprawling litigation involving the drug Risperdal, the penalty that South Carolina sought and obtained stands out as a particularly egregious example of a grossly disproportionate sanction. Then-AG Henry McMaster of South Carolina sued

*“In recent years, state AGs have either overlooked or, worse, intentionally disregarded these bedrock constitutional principles in their crusade to deliver money to their states and further their political agendas.”*



Janssen Pharmaceuticals in 2007, accusing the company of violating the state's Unfair Trade Practices Act. In July 2011, after a four-year investigation, Janssen was ordered to pay \$327 million in civil penalties for over 500,000 technical violations of the state's act. Each violation consisted of sending out individual "Dear Doctor" letters or package inserts that were found to be misleading as to the safety and efficacy of Risperdal.<sup>162</sup> Although the South Carolina Supreme Court cut the penalty to \$136 million in February 2015, the fact remains that the manufacturer was ordered to pay a nine-figure penalty for statutory violations that were never proven to have caused harm to anyone.

Similarly, state supreme courts in Arkansas and Louisiana also reversed mammoth penalties verdicts in cases involving Risperdal.<sup>163</sup> The Arkansas Supreme Court reversed a penalties verdict of \$1,194,370,000 under the Medicaid Fraud False Claims Act and a penalties verdict of \$11,422,500 under the Arkansas Deceptive Trade Practices Act.<sup>164</sup> The Louisiana Supreme Court reversed a penalties verdict of \$257,679,500 under the Louisiana Medical Assistance Programs Integrity Law.<sup>165</sup> Both cases centered on allegations that Janssen deceptively marketed the drug Risperdal. Although the Arkansas, Louisiana, and South Carolina rulings all turn on different legal issues, they appear to confirm the excessive nature of the penalties sought by state

AGs, and reflect judicial recognition that reasonable limitations must be placed on AG pharmaceutical litigation.

The gargantuan award in South Carolina in particular has garnered criticism from several corners. South Carolina State Senator Paul Campbell spoke out publicly against the verdict, contending it was bad for the state's business and resulted from "two questionable findings" by the South Carolina Supreme Court.<sup>166</sup>

First, the court concluded that the company did not have a sufficient basis in 2003 and 2004 to represent that Risperdal caused less weight gain and a lower risk of diabetes than its competitor, despite the fact that the state's experts admitted in the intervening years that those claims turned out to be true.

Second, the court concluded that the side effects of the drug were listed on the wrong section of the label, even though the FDA approved its placement and there was no evidence on the record that physicians were misled by the label.<sup>167</sup>

This misconduct is hardly so egregious as to justify a verdict "12 times higher than any other affirmed appellate award in the state's history."<sup>168</sup> As Senator Paul Campbell pointed out, the highest award prior to the Janssen ruling was \$11 million "against an insurance company that refused to honor a policy for an AIDS victim. In that case there was a real victim with a real case."<sup>169</sup>

In the South Carolina Risperdal case, by contrast, there was no “evidence that any patient was harmed” by the manufacturer’s conduct.<sup>170</sup> “Since there is no victim, only two parties will benefit: trial lawyers employed by the state who will make millions, and the State of South Carolina, which will enjoy a one-time windfall.”<sup>171</sup>

The excessive nature of the South Carolina Risperdal verdict is further illustrated by a comparison with its agreement to resolve criminal and civil probes over sales and marketing of Risperdal and other medications on a broader scale in 2014.<sup>172</sup> That settlement was entered into with 36 states and the District of Columbia, with each state receiving an average award of \$4.89 million.<sup>173</sup> In view of that average payout, South Carolina’s \$136 million award is undoubtedly excessive.

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# Conclusion

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The examples highlighted in this paper paint a picture of an unsettling legal landscape in which companies doing business in the United States are the targets of enforcement abuse. These abuses come in many forms, including overly aggressive parallel proceedings, overzealous exercise of prosecutorial discretion, burdensome pile-on litigation, and excessive fines and penalties.

Far from promoting justice, these abuses are hurting American businesses by subjecting them to an endless cycle of litigation, inconsistent regulatory standards, and debilitating injunctive relief and civil penalties that drain corporate resources. And the impact on the American consumer is no less pernicious, as the economic and reputational costs to American businesses translates into reduced investments in research and development and are ultimately passed on in the form of higher prices in the marketplace.

The current enforcement trends demonstrate that two overarching principles key to the sound administration of justice must be restored: Regulators should collectively promote rational enforcement of the law; and public policies regarding enforcement should be designed to encourage cooperation and compliance.

As to the first principle, it is irrational to punish a wrongdoer multiple times for the same malfeasance and for state and

federal agencies to compete to wield the biggest stick, wasting public resources on duplicative efforts. Rational enforcement will restore trust in regulators as they tailor the punishment to better fit the crime.

As to the second principle, it should be recognized that the business community generally shares the desire to prevent and deter corporate wrongdoing. Companies evaluating the risks of non-compliance have a right to know upfront what potential civil and criminal liabilities exist and what benefits they will derive from compliance and cooperation with authorities. Businesses want and deserve more certainty in carrying out their compliance responsibilities.

A national conversation on the state of government enforcement, informed by the examples set forth in this paper, is needed in order to restore these key principles through reforms and safeguards at both the state and federal levels. Reforms should address the pile-on of multiple, duplicative government agency involvement, and the

goal of fostering compliance by providing more certainty. Reforms could include the following:

- Only a single government enforcement entity should be allowed to take action with respect to particular corporate conduct, with other entities standing down once an enforcement investigation or other process has begun.
- To the extent that state authorities are involved, they should be prohibited from entering into settlement agreements that effectively regulate conduct in other states.
- Enforcement actions should be limited to situations in which the relevant law and regulations made clear at the time of the alleged violation that the conduct at issue was unlawful.
- To avoid uncertainty and promote transparency, standards should be established (and publicized) for calculating fines and penalties, to ensure that the punishment is proportionate to the damages and to avoid use of threatened massive penalties to coerce settlement.

- Also with regard to transparency, policies should be put into place to encourage communication with the regulated community and to clarify perceived ambiguities over enforcement policy and interpretation.
- Enforcers should be prohibited from retaining the proceeds of enforcement actions for their own use or from steering public settlement money to their preferred projects and charities.

These are just a few of the ways to address the over-enforcement problem. Any reforms in this area should suggest meaningful policies that will incentivize and promote compliance and cooperation. A reasoned dialogue among policy makers, business leaders, regulators, and the public will undoubtedly uncover others that will benefit all sectors of society.

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