



U.S. CHAMBER
Institute for Legal Reform

Unfair Practices or Unfair Enforcement?

Examining the Use of Unfair and Deceptive Acts and Practices (UDAP) Laws by State Attorneys General

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U.S. CHAMBER
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Executive Summary

Some state attorneys general (AGs) lawsuits, explored by this report, bear little resemblance to traditional government enforcement of consumer protection laws. These cases are often brought by states at the urging of contingency fee lawyers, involve practices already regulated by government agencies, and seek civil penalties that are disproportionate to the alleged misconduct or consumer loss. Money from the resulting settlements and judgments is doled out by AGs to outside organizations or used for pet projects with no relation to the lawsuits. While these types of enforcement actions are the exception, not the rule, they are becoming increasingly common. They pose a threat to good government, sound public policy, and due process.

Consumer protection laws provide state AGs with sweeping authority to address improper business practices. As their name suggests, most state Unfair or Deceptive Acts and Practices (UDAP) laws broadly prohibit any conduct that can be viewed as “unfair” or “deceptive.” (These laws are also frequently referred to as Consumer Protection Acts or Unfair and Deceptive Trade Practices Acts.) The vagueness of these terms provides substantial power to state AGs, which makes it all the more critical that AGs responsibly exercise their enforcement discretion.

Normally, state AGs and their staffs quietly and effectively use UDAP laws to protect the rights of consumers. They receive complaints, conduct investigations, and mediate disputes. State AGs take action to immediately stop illegal conduct and, where appropriate, seek refunds or other relief for affected consumers. This day-to-day work is generally uncontroversial and can benefit the public.

The types of state UDAP enforcement actions explored in this report are different. They often share a combination of four common elements:

“ When lawyers are compensated based on a percentage of damages and fines imposed, they invariably recommend filing an action and seeking the highest penalties authorized by law. ”

1. The enforcement actions are frequently driven by private lawyers, not consumer complaints;
2. The actions often target conduct already closely regulated by government agencies charged with protecting the public;
3. The actions seek civil penalties that dwarf actual harm to consumers, if any; and
4. The settlements and judgments reached do not reimburse injured consumers or advance consumer protection efforts related to the conduct at issue, but result in payments to private lawyers and politically-popular groups and causes.

Who Creates and Controls the Litigation?

Unlike traditional state AG consumer protection claims, most of the lawsuits examined in this report originated with private lawyers who developed and pitched the action to a state AG rather than from complaints filed by actual consumers. In some cases, AGs have even delegated the state's subpoena power to private lawyers. The result of any such investigation is largely preordained. When lawyers are compensated based on a percentage of damages and fines imposed, they invariably recommend filing an action and seeking the highest penalties authorized by law. Rather than apply the type of neutral law enforcement expected of state AGs, these actions are prone to target businesses viewed as having the deepest pockets.

How Do UDAP Actions Address Regulated Business Practices?

The enforcement actions that raise concern often do not involve typical consumer transactions that led states to enact UDAP laws. These lawsuits do not, for example, respond to instances in which consumers were bamboozled by a slick salesperson into purchasing a worthless product or fraudulently enticed into parting with their money for a service they did not receive. Rather, these AG actions often challenge practices that are already closely regulated by federal and state government agencies charged with protecting the public interest.

Critical Differences Between Federal and State Enforcement

Most states adopted UDAP laws in the 1960s and 1970s to supplement federal consumer protection enforcement. Today, every state has a consumer protection statute. While these laws are sometimes referred to as “Little FTC Acts,” there are critical differences between UDAP laws and the Federal Trade Commission Act (FTC Act).

When Congress enacted the FTC Act, it addressed concerns that the vagueness of the terms “unfair” and “deceptive” could lead to abusive lawsuits and punish businesses without prior notice that the conduct at issue was improper. First, Congress placed the power to define and identify prohibited acts with a nonpartisan Commission, the FTC. Second, Congress recognized that the FTC Act is “preventative

and cooperative, rather than penal.” The FTC can immediately act to stop deceptive practices and seek restitution for consumers. The FTC can and does impose substantial penalties on businesses that violate a cease-and-desist order or consent agreement, or that had clear notice that conduct is prohibited.

Unlike the federal law, most UDAP laws allow the state (usually through the attorney general) to immediately seek substantial civil penalties. In addition, some state AGs have hired outside lawyers on a contingency fee basis to enforce UDAP laws, a practice not used by federal agencies. These differences lead to a potential for abuse in state enforcement of UDAP laws that is not present in federal enforcement.

Pharmaceutical manufacturers are a prime target, and other regulated businesses are also in the crosshairs. Plaintiffs’ lawyers representing states have, for example, improperly used informal letters in which FDA staff express concern regarding the marketing of a drug as a basis for seeking civil penalties, taking advantage of the manufacturer’s cooperation to promptly resolve the issue. Others have targeted unpopular industries, such as nursing homes, claiming that practices that comply with regulations governing the industry nevertheless violate UDAP laws.

How are Civil Penalties Calculated?

The UDAP actions highlighted in this report do not seek restitution for consumers who suffered a loss. Instead, these suits demand civil penalties regardless of whether anyone was actually misled or otherwise harmed. By creatively multiplying the maximum civil penalty (which ranges from \$1,000 to \$50,000 depending on the state at issue) “per violation,” plaintiffs’ lawyers representing the state can transform a single act into a multimillion dollar penalty.

“Funds obtained through many UDAP lawsuits enrich the plaintiffs’ lawyers who bring them and advance the political aspirations of state officials who hire those lawyers.”

These already extraordinary civil penalties rise exponentially when similar suits brought in multiple states and through coordinated multi-state actions involving the same conduct are taken into account. In addition, AG enforcement actions often target businesses that have already spent significant sums defending against consumer class actions and other lawsuits involving the same alleged practices, which may be brought by the same private lawyers driving the UDAP action. The unpredictable, massive liability exposure places heavy pressure on businesses to settle even meritless claims.

Where Does the Money Go?

Funds obtained through many UDAP lawsuits enrich the plaintiffs’ lawyers who bring them and advance the political aspirations of state officials who hire those lawyers. In many instances, consumers and taxpayers see little, if any, of the funds recovered through UDAP settlements and judgments. Instead, state AGs often distribute the funds to politically popular nonprofits and causes—from stopping gang violence to providing drug treatment—with a highly attenuated or no connection to the litigation. Such AG practices have drawn the ire of state governors and legislators as an intrusion into their role of budgeting and appropriating state funds.

Future Targets

While many of the actions discussed in this report target pharmaceutical manufacturers, it is likely that the same troubling playbook will be used against an increasingly broad array of businesses. Already, some of these practices have arisen in cases involving nursing homes, mortgage lenders, and automobile manufacturers, among others. In the future, businesses that are subject to a data breach, whether as a result of a hacker or an error, may face UDAP enforcement actions that go too far. Food and beverage makers, which have experienced a surge of private consumer class actions, are already in the sights of lawyers making hiring pitches to state AGs.

Recommendations for Reform

This report offers commonsense options for legal reform that would address problematic enforcement of UDAP laws. These proposals were developed based on existing state laws and court decisions. They address the specific types of practices documented in this report and are intended to generate ideas for state-specific amendments to UDAP laws.

Government Enforcement Driven by Contingency Fee Lawyers

A common thread through many of the UDAP enforcement actions discussed in this report is that they did not originate with a government-identified need to protect consumers. Rather, private plaintiffs' lawyers developed the theories of liability, pitched the UDAP claims to state AGs, and then litigated them in exchange for a contingency fee. This process is rife with conflicts of interest and ethical and constitutional concerns. It also raises the core question of whether such lawsuits are brought to protect consumers or to benefit private lawyers and the politically-motivated AGs who hire them.

The troubling and growing practice of state AGs delegating state enforcement power to private contingency fee lawyers has been widely documented in past ILR reports,⁷ congressional testimony,⁸ think tank papers,⁹ legal scholarship,¹⁰ and even in a Pulitzer Prize-winning *New York Times* exposé.¹¹ Although an executive order prohibits the federal government from hiring private lawyers on a contingency fee basis to pursue consumer protection or other enforcement actions,¹² this practice is widespread with respect to UDAP claims brought by state AGs.

Some state AGs have hired lawyers to represent the state through no-bid contracts, providing political supporters with lucrative opportunities. For example, outside lawyers hired by former Louisiana AG Buddy Caldwell collected more than \$54 million during his tenure.¹³ The law firms he hired included that of his campaign manager, T. Allen Usry, and his campaign treasurer, E. Wade Shows, whose firms and relatives gave thousands to his campaigns.¹⁴ Even after the Louisiana legislature passed a law making it absolutely clear that hiring outside lawyers on a contingency fee basis without legislative authorization is prohibited, AG Caldwell, who was defeated at the polls in November 2015, contracted out seven new UDAP lawsuits by claiming

they fell under retention agreements approved before the law took effect.¹⁵ His successor, AG Jeff Landry, cancelled many of the contracts entered by Caldwell, citing a “pattern of abuse.”¹⁶

In some cases, AGs have even handed over to profit-driven lawyers the state’s broad subpoena power, allowing lawyers to “investigate” until they reach the foregone conclusion to bring an enforcement action—the only way the law firm will get paid. For instance, the Pennsylvania Attorney General’s Office has approximately 180 lawyers on staff, but recently-resigned AG Kathleen Kane had hired four private law firms that donated nearly \$200,000 to her campaigns from 2011 to 2013, to conduct these investigations.¹⁷ At least nine law firms have contracts with the office, and their employees collectively gave about \$362,199 to her campaign.¹⁸

Contingency fee lawyers exercise significant control over the theories alleged, the day-to-day litigation of the case, and, ultimately, the state’s settlement of the case.

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Delegating government law enforcement authority to financially-motivated private lawyers also makes it difficult for an AG to work with a company to promptly address concerns and reimburse anyone who was harmed by improper practices. When private lawyers receive a share of the amount collected by the state, there is a strong incentive to seek the highest possible civil penalties, even when not justified by the business’s conduct or the public interest.

Some retention agreements between states and private lawyers have even limited the ability of a state to settle for non-monetary relief. As a result, states that have hired outside counsel have foot-dragged in some cases for large paydays, rather than promptly and reasonably resolved concerns.

Recent Examples

PENNSYLVANIA: GAME, SET, MATCH: PRIVATE FIRMS INVESTIGATE, ENFORCE, AND PROFIT

In 2012, then-Pennsylvania AG Linda Kelly hired DC-based plaintiffs’ firm Cohen Milstein, Sellers & Toll¹⁹ to investigate the state’s nursing homes. According to the *Philadelphia Inquirer*, “it was Cohen Milstein that dreamed up the initiative and sold it to the Attorney General’s Office to obtain a no-bid contract.”²⁰

Cohen Milstein contributed \$10,000 to AG Kelly’s successor, Kathleen Kane, who continued the litigation.²¹ The law firm also provided additional contributions to the Democratic Attorneys General Association, which also helped Kane.²² All in all, Kane

received \$350,000 in campaign donations from law firms she hired to bring lawsuits on behalf of the state.²³

In February 2014, Kane amended the agreement with Cohen Milstein to boost its payment from \$17 million to \$21 million of the first \$100 million collected from the nursing homes.²⁴ The agreement was later amended yet again to drop a provision that was particularly vulnerable to constitutional challenge. That provision barred the state from settling the lawsuit other than for a financial payment. The state could not, for example, accept a promise from the facilities to increase staffing or otherwise improve conditions.²⁵ Instead, the agreement now allows a settlement that provides injunctive relief but no financial recovery, yet requires the AG's office "to use its best efforts to negotiate for the payment of reasonable attorneys' fees as a settlement term."²⁶

Between March and August 2014, the state served subpoenas on for-profit nursing homes operating in Pennsylvania.²⁷ These subpoenas were issued by a Cohen Milstein paralegal acting as "representative of the attorney general authorized to serve as subpoena" in conjunction with a deputy state attorney general, and served by the law firm.²⁸ A lawyer for the nursing home chains has observed that the lawsuit appears to target facilities based on their apparent wealth, as the action does not include not-for-profit establishments to which the claims could equally apply.²⁹

In July 2015, AG Kane reached the foregone conclusion that the nursing homes violated the state's UDAP law, claiming that the facilities' staffing levels were inadequate

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to support statements of quality service included in marketing. She filed a lawsuit against the facilities in the Commonwealth Court of Pennsylvania.

The nursing homes are fighting the contingency fee arrangement in court, in addition to defending their compliance with existing regulations governing staffing levels.³⁰ In January 2016, a state appellate court found that the nursing homes lacked standing to challenge the AG's agreement with outside counsel, allowing the litigation to continue.³¹

KENTUCKY: A "DISAPPOINTINGLY CASUAL APPROACH"

In 2009, Kentucky AG Jack Conway filed a lawsuit against Merck under the Kentucky Consumer Protection Act for claims related to the company's marketing of Vioxx, providing an example of how outside lawyers develop and control the litigation. The state sought civil penalties in the amount of \$2,000 for each violation and \$10,000 for each violation targeting a consumer over the age of sixty-five.

Roughly one year after filing the claim, Conway retained an outside law firm to litigate the case on a contingency fee basis.

Merck sought relief in federal court, arguing that the outside counsel, Garmer & Prather, appeared to be calling all the shots. The pharmaceutical maker presented specific examples showing how the government attorney charged with overseeing the litigation lacked real involvement.³² Merck pointed out that the contract required that the outside counsel assume a “lead role in investigating and preparing [the] litigation.”³³ The AG failed to make any “substantive revisions” or contributions to court filings, which included a list of alleged violations and penalties sought that were almost identical to one produced by Garmer & Prather on behalf of the State of Alaska.³⁴ The briefs filed in the multidistrict litigation were submitted by outside counsel and the letters to the court as well as the rejection of the settlement offer were submitted on Garmer & Prather letterhead.³⁵ The government attorney, who purportedly supervised the litigation, only called into some status conferences, never spoke on the record, could only identify the role of 7 of the state’s 65 witnesses, and did not even know if the state had retained expert witnesses.³⁶

The federal district court considering the case, however, did not find the government’s lack of knowledge of the details of its own enforcement action troubling. Rather, it viewed the government’s attorney as “performing badly on a few ‘pop quizzes.’”³⁷ But the court did find one close call: the list of 45 claimed violations of the Kentucky

Consumer Protection Act was cut-and-paste from one produced by the same outside counsel in a lawsuit brought on behalf of the State of Alaska.³⁸ The court viewed the government’s lack of involvement in shaping the claims as a “disappointingly casual approach.”³⁹

Nevertheless, the district court concluded that the AG retained and exercised decision-making authority in the underlying litigation and Merck’s due process rights were not violated.⁴⁰ Merck appealed, but the underlying litigation settled before the U.S. Court of Appeals for the Sixth Circuit had an opportunity to rule.

NEVADA: AG SETTLES ONLY AFTER SANCTIONS

Nevada was the last state to settle a UDAP enforcement action with a mortgage lender, and did so only after a court took the rare action of sanctioning a state AG.

Nevada AG Catherine Cortez Masto hired attorneys at Cohen Milstein to sue Lender Processing Services (LPS) over its alleged misconduct in providing support services for mortgage lenders.⁴¹ As in Pennsylvania, the firm or its lawyers donated generously to the Democratic AGs Association.⁴² As the *Wall Street Journal* found, “The Democratic AGs Association has in turn contributed to Ms. Masto, including \$10,000 in 2009, the year she signed up Cohen Milstein” with a no-bid contract.⁴³ The following year six partners at the firm donated to her election campaign.⁴⁴

The state alleged that the mortgage lender committed 70,000 violations of the state’s Deceptive Trade Practices Act.⁴⁵ The AG

“As a lawyer for the company observed, the Nevada case continued ‘because they have a class-action law firm running this. The attorney general is not running this.’”

took an aggressive approach in the press, accusing the company of running “an assembly line sweatshop, churning out documents and foreclosures as fast as new requests came in and punishing network attorneys who failed to keep up the pace.”⁴⁶

Forty-six states and the District of Columbia settled UDAP claims with the company in January 2013,⁴⁷ following earlier settlements with three individual states.⁴⁸ Nevada, reportedly the only state to hire contingency fee lawyers to pursue LPS,⁴⁹ sought a bigger payday. There, Cohen Milstein stood to gain 15% of any settlement or judgment. The agreement that Nevada entered gave Cohen Milstein “virtual veto power” over any settlement offer.⁵⁰ Since the AG’s office agreed not to settle for injunctive relief unless the defendant provided costs and hourly fees for the law firm’s services, the arrangement gave the firm leverage to push for the highest monetary settlement. In fact, Nevada’s actions threatened to unravel LPS’s settlement with other states because the agreement allowed states to renegotiate if any state gets a different deal.⁵¹

As a lawyer for the company observed, the Nevada case continued “because they have a class-action law firm running this. The attorney general is not running this.”⁵²

The company challenged the AG’s arrangement with Cohen Milstein as violating a Nevada law mandating legislative approval of the AG’s use of outside counsel, among other grounds. As this challenge to the arrangement was pending in the state supreme court,⁵³ Clark County District Judge Elizabeth Gonzalez ordered the state and Cohen Milstein to produce evidence of the alleged number of consumer protection violations. After they failed to do so, Judge Gonzalez imposed sanctions in January 2014, ordering the state to cover the company’s legal costs associated with its attempts to obtain this evidence.⁵⁴

During the sanctions hearings, Judge Gonzales was skeptical of Cohen Milstein’s role, chiding:

One would think that when the state of Nevada enters into an agreement with a firm from outside the state of Nevada to handle a case for them that [the state] would receive some benefit from entering into that arrangement. It does not appear that the resources which were scarce from the Attorney General’s Office which allegedly caused them to hire your firm have been added to based upon the review of the information that has been provided to the Court.⁵⁵

Two weeks after Judge Gonzalez’s sanctions order, before the AG’s office was required to pay the company’s substantial legal fees, AG Masto settled the case with LPS for \$6 million.⁵⁶ As a result, the Nevada Supreme Court did not rule on LPS’s challenge to the AG’s hiring of Cohen Milstein.

ARKANSAS AND MISSISSIPPI: PRIVATE LAW FIRM HOLDS OUT FOR BIGGER PAYDAY

In multi-state litigation claiming that Eli Lilly violated UDAP and other laws by marketing Zyprexa for purposes other than treating schizophrenia or bipolar disorder, plaintiffs’ firm Bailey Perrin Bailey (BPB) was the main settlement holdout. BPB handled Zyprexa litigation for Arkansas, Mississippi, and Pennsylvania, and was among a group of law firms representing South Carolina. The Arkansas and Mississippi arrangements especially raised eyebrows, as Texas-based BPB and its lawyers had reportedly donated

\$70,000 to the Arkansas Democratic Party and \$75,000 to Mississippi Attorney General Jim Hood’s reelection campaign.⁵⁷

Thirty-three states that sued Lilly based on similar allegations entered a \$62 million settlement in October 2008.⁵⁸ Several additional states (also represented by outside counsel) followed, entering individual settlements. With the exception of Pennsylvania, the states represented by BPB were among the few hold outs.⁵⁹

These “slash and burn” tactics backfired after a federal judge dismissed most of Mississippi’s claims.⁶⁰ Faced with the possibility of collecting nothing, Mississippi entered an \$18.5 million settlement with Eli Lilly in February 2010 — an amount that was a fraction of the UDAP civil penalties its outside lawyers had sought.⁶¹ Around that time, Arkansas settled for the same amount.⁶²

In the settlement resolving the Mississippi and Arkansas litigation, respectively, private lawyers including BPB received \$3.7 million and \$2.8 million.⁶³

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CONSTITUTIONALITY OF OUTSOURCING CIVIL PENALTIES TO CONTINGENCY FEE LAWYERS

Businesses targeted by private law firms wielding the state AG’s enforcement authority have repeatedly challenged such arrangements as violating their due process rights, exceeding the AG’s authority, and on other grounds. Since private contingency fee counsel will not be paid at all for their services unless there is a recovery, for all practical purposes, the arrangement negates the possibility that the state would exercise its discretion not to seek penalties.

“ While most courts have not categorically barred AGs from hiring attorneys on a contingency fee basis to litigate civil cases, several have found that a state cannot abrogate its enforcement authority to profit-driven outside lawyers. ”

Moreover, UDAP cases are not ordinary civil cases seeking recovery of amounts due to the state, but enforcement actions akin to criminal proceedings. Using a contingency fee arrangement in such actions provides a strong incentive to pursue the maximum number of violations and maximum amount of penalties, regardless of what the evidence shows or the public interest requires. Private lawyers representing a state have little or no incentive to pursue nonmonetary remedies, such as requiring a company that made a misstatement to issue a correction.

The U.S. Supreme Court has long recognized the potential for abuse where the government subjects a defendant to prosecution by a private lawyer whose judgment is clouded by a financial stake or other personal stake in the outcome. The Court has warned that a “scheme injecting a personal interest, financial or otherwise,

into the enforcement process may bring irrelevant or impermissible factors into the prosecutorial decision and in some contexts raise serious constitutional questions.”⁶⁴ The Court has also recognized that private attorneys appointed to represent the government “certainly should be as disinterested as a public prosecutor who undertakes such a prosecution.”⁶⁵

State high courts and federal district courts have scrutinized AG delegations of authority to private lawyers in various types of litigation.⁶⁶ While most courts have not categorically barred AGs from hiring attorneys on a contingency fee basis to litigate civil cases,⁶⁷ several have found that a state cannot abrogate its enforcement authority to profit-driven outside lawyers. Courts have required government lawyers to exert control over the litigation. In practice, however, this test has been a fairly easy one for an AG to satisfy, as Kentucky AG Conway’s action against Merck discussed earlier shows.⁶⁸ It often only requires including in the fine print of a retention agreement a statement that the government retains ultimate control over the litigation and a minimal showing of government involvement in the litigation and any settlement. Other courts, such as Pennsylvania’s high court, have insulated agreements between state officials and private lawyers from judicial scrutiny by finding defendants lack standing to challenge them, further providing a need for legislative action.⁶⁹

Reform Options

ADOPT LAWS REQUIRING TRANSPARENCY IN THE STATE'S HIRING AND PAYING OF OUTSIDE COUNSEL

Since 2010, 15 states have adopted safeguards that apply when an AG or other state official retains outside counsel to represent the state.⁷⁰ These laws ameliorate some of the concerns present in UDAP and other state enforcement actions that are driven by private contingency fee lawyers by:

- Requiring government officials who have authority to hire outside counsel to make a written finding that hiring outside counsel is cost-effective and in the public interest before hiring private lawyers;
- Subjecting the hiring process to competitive public bidding;
- Posting contingency fee contracts and payments made to private lawyers on a public website;
- Requiring outside counsel to maintain detailed time and expense records;

- Mandating that government lawyers maintain control over the litigation;
- Placing with the state exclusive authority to settle a case;
- Placing a sliding scale on contingency fees based on the amount recovered, along with a maximum fee cap; and
- Precluding lawyers from collecting fees based on a percentage of the civil penalties imposed.

In addition, some states require the AG to obtain legislative approval before retaining an attorney on a contingency fee basis. Louisiana enacted such a law in 2014.⁷¹ A 2015 Nevada law requires the approval of the state legislature's Interim Finance Committee to commit money for paying a contingency fee before entering such a contract.⁷² Most recently, a New Hampshire court found that state law does not allow the attorney general to use a contingency fee agreement as an "end run" to avoid the need for a legislative appropriation for hiring outside counsel.⁷³

Unprincipled Regulation and Enforcement

UDAP laws provide a means to protect consumers where business practices are not already closely regulated by the government. Some state AGs, however, have usurped the power of those charged with protecting public health and safety, imposing their own requirements and penalties. For example, AGs have brought a surge of enforcement actions against drug makers challenging marketing practices regulated by the FDA. The problem extends to other businesses that comply with regulations, but find themselves in the crosshairs of state AGs and contingency fee counsel. These types of lawsuits create confusion, result in excessive regulation, and punish businesses even when they comply with their legal obligations.

State UDAP laws broadly prohibit “unfair” or “deceptive” practices in the sale of products and services to consumers. What conduct falls within these amorphous terms is generally determined on a case-by-case basis, either through government enforcement actions or private lawsuits.

Most UDAP laws recognize the value of consistency between the policymaking of regulatory agencies charged with protecting consumers in a particular area and UDAP enforcement actions. Such congruence respects the authority and expertise

of government agencies, and provides predictability and fairness for businesses that rely on government decision-making. Moreover, there are often alternative means in place, often through administrative systems, for addressing consumer complaints regarding regulated conduct.

For these reasons, about two-thirds of state UDAP laws exempt from their scope conduct that is regulated, permitted, approved, or specifically authorized by state and/or federal agencies. The language of these provisions varies from state to state.

A few state laws only exempt conduct permitted by the FTC. Other state laws do not apply to conduct regulated by specific state entities, such as a state insurance commission or public utility board. The most common form states that the UDAP law does not extend to conduct permitted by a state or federal agency. In some states that lack a statutory provision, courts have adopted these principles.⁷⁴

Application of this sound policy, however, is not consistently and predictably applied, exposing businesses that have carefully followed the requirements of one government agency to state AG UDAP enforcement actions elsewhere.

Recent Examples

USE OF INFORMAL FDA WARNING LETTERS AS PREMISE FOR MASSIVE CIVIL PENALTIES

The FDA closely monitors prescription drug marketing. Each year, the FDA's Office of Prescription Drug Promotion (OPDP) (formerly the Division of Drug Marketing, Advertising and Communications) reviews thousands of direct-to-consumer advertisements, "Dear Doctor" letters, and other materials disseminated by pharmaceutical companies.⁷⁵ Occasionally, OPDP staff identify a concern with such material, finding that it does not present a balanced assessment of the benefits and risks of the drug, or that it omits pertinent information.⁷⁶ When it does, OPDP issues a warning letter, which the FDA's own guidelines recognize is "informal," "advisory," and "do[es] ... not commit FDA to taking enforcement action."⁷⁷

The FDA explained to the U.S. Supreme Court that warning letters do "not mark the consummation of FDA's decision-making process," are "not based on a formal and complete administrative record," are merely "tentative," and "do not constitute final agency action."⁷⁸ The FDA has also reported that "[s]ubordinate FDA officials issue hundreds of warning letters each year."⁷⁹ Unlike formal FDA advisory opinions, warning letters are merely the judgment of particular agency employees and "do ... not necessarily represent the formal position of the FDA, and do ... not bind or otherwise obligate or commit the agency to the views expressed."⁸⁰ There is no hearing or any other due process before the agency issues such a letter. Nor is there any finding that the manufacturer's conduct actually misled doctors or their patients. Warning letters are not subject to challenge in court.⁸¹

Typically, a warning letter requests that the manufacturer stop running the advertisement or issue a corrective letter to healthcare providers. Manufacturers usually voluntarily and promptly comply with the FDA's request. According to the FDA, "nearly all of [the issued warning letters] are resolved through discussions between FDA staff and those in the regulated industry."⁸² After the FDA verifies that the manufacturer has taken corrective action that adequately addresses the concerns expressed in the warning letter, the FDA closes the matter.⁸³

“ Despite the informal nature of such letters, some state AGs misleadingly wave FDA warning letters in front of judges and juries as damning evidence of UDAP violations. ”

Despite the informal nature of such letters, some state AGs misleadingly wave FDA warning letters in front of judges and juries as damning evidence of UDAP violations. As a result, when the FDA identifies a concern, and a drug maker responds as requested, the manufacturer is potentially subject to fifty-one lawsuits by state AGs, each seeking astronomical civil fines.

ARKANSAS: \$1.2 BILLION JUDGMENT RESULTED FROM ADMISSION OF UNDULY PREJUDICIAL LETTER

Former Arkansas AG Dustin McDaniel brought a UDAP action against Janssen in 2007, after plaintiffs’ law firms approached his office.⁸⁴ The state alleged violations of the Arkansas Deceptive Trade Practices Act (DTPA) and the Arkansas Medicaid Fraud False Claims Act based on statements Janssen made in a 2003 letter sent to physicians about Risperdal, a drug that treats schizophrenia and symptoms of bipolar disorder. The state’s UDAP claim relied on a 2004 warning letter in which FDA staff expressed concern that Janssen’s letter to physicians did not adequately address the risks of hyperglycemia and diabetes associated with the drug. Although Janssen disagreed with the FDA’s position, it promptly sent a corrective letter to healthcare providers. This satisfied the FDA’s concerns.

AG McDaniel argued to a Pulaski County jury that the warning letter was definitive proof of violations of federal law that supported his DTPA claims. The FDA’s warning letter was referred to repeatedly during the trial, including at least 15 times in closing arguments alone.⁸⁵ McDaniel alleged 4,569 DTPA violations, based on the number of “Dear Doctor” letters sent to healthcare providers. Upon a jury verdict for the state, the circuit court imposed a \$2,500 fine per letter for a total of \$11,422,500.⁸⁶ The court awarded an additional \$1.2 billion under the state’s Medicaid fraud statute, imposing a \$5,000 fine for each of 238,974 Risperdal prescriptions filled during the applicable time frame without proof that anyone was injured.⁸⁷

In 2014, the Arkansas Supreme Court reversed the entire judgment. It found that the FDA warning letter was inadmissible as evidence because the letter was both prohibited hearsay and, even if it had fallen within an exception to the hearsay rule, it was more prejudicial than probative.⁸⁸ As a government-issued document, the FDA letter carried inordinate weight with the jury, yet it was the result of only an informal investigation, the court found. The Arkansas Supreme Court also threw out \$180 million in attorney’s fees and costs awarded to the state on the two claims.⁸⁹

WEST VIRGINIA: PENALTIES PREMISED ON FDA LETTER DEPRIVED MANUFACTURER OF ABILITY TO FULLY AND FAIRLY DEFEND ITSELF

Years earlier, a similar lawsuit brought by West Virginia's AG suffered a similar fate. Then-AG Darrell McGraw, Jr. brought claims under his state's Consumer Credit and Protection Act relying on the same 2004 warning letter to Janssen concerning its "Dear Doctor" letter about Risperdal. AG McGraw's lawsuit also alleged a UDAP claim based on a separate FDA warning letter issued that year regarding the company's marketing of Duragesic, a pain reliever.

As with the Risperdal letter, Janssen disputed the FDA's assertions, but voluntarily complied by sending corrective information to doctors. McGraw's case was based *entirely* on the statements and

omissions included in the letters warning to Janssen.⁹⁰ The AG sought a \$5,000 civil penalty for each letter sent by the company to a West Virginia doctor. The Circuit Court of Brooke County found that the FDA's warning letters conclusively established a violation of the state's UDAP and imposed a \$4,475,000 civil penalty.⁹¹

The West Virginia Supreme Court of Appeals reversed, recognizing that when the FDA issues a warning letter it does not provide due process safeguards, such as prior notice, a hearing, or the ability to appeal.⁹² The letter indicates only FDA staff's *belief* that a violation has occurred, but is not conclusive.⁹³ "It is fundamental," the court found, "that every defendant is entitled to defend themselves against allegations of misconduct."⁹⁴

“ In 2014, the Arkansas Supreme Court reversed the entire judgment. It found that the FDA warning letter was inadmissible as evidence because the letter was both prohibited hearsay and, even if it had fallen within an exception to the hearsay rule, it was more prejudicial than probative. ”

SOUTH CAROLINA: MISCHARACTERIZATIONS OF WARNING LETTER LEADS TO UPHOLDING OF PENALTIES BY SC SUPREME COURT

A similar court judgment withstood appellate review in South Carolina. There, then-AG Henry McMaster filed an action against Janssen under the South Carolina Unfair Trade Practices Act premised, in part, on the company's sending the same "Dear Doctor" letter to 7,184 physicians in his state. Private lawyers hired by AG McMaster to represent the state⁹⁵ used Janssen's cooperation with the FDA as proof that its "Dear Doctor" letter violated the Act, misrepresenting the company's options in the process. Plaintiffs' lawyer Donald Coggins, Jr. of Harrison, White, Smith & Coggins, P.C. stated in his opening argument:

[W]hen [DDMAC] came along and issued that warning letter in April and ordered corrective action I think it's instructive what Janssen did. They could've appealed it, they could have contested it, they could have gone to court about it, they could have asked for some other type of sanction but what did they do? They sent it out just like the FDA told them [to] [A]nd the [correction] letters clearly show an acknowledgement that they did wrongdoing ... ⁹⁶

Two weeks later, in closing arguments, Coggins' colleague, John Simmons, repeated these misleading assertions:

The FDA concludes that the dear doctor letter was false and misleading in a number of areas ... The FDA said you not only made affirmative misrepresentations in that dear doctor letter, you omitted material information which is to say as being untruthful,

which is to say as being imprudent, which is to say to be submitted unfair and deceptive ... [A]fter they received that warning letter, these defendants folded like a cheap suit. The FDA wrote them that [warning] letter in April and said false and misleading ... It called them on what they did. These defendants caved in immediately [and sent a correction letter].⁹⁷

Janssen's counsel attempted to show the inaccuracies in these statements by pointing out that "warning letters are informal," "they're advisory," and "[t]hey're not subject to appeal to anyone."⁹⁸ But the jury determined that Janssen engaged in unfair or deceptive practices in its marketing, and the trial court judge determined that each "Dear Doctor" letter was a separate violation and imposed a \$4,000 per letter penalty for a total of \$28.7 million.⁹⁹

Although the South Carolina Supreme Court found that Janssen's conduct "likely had little impact on the community of prescribing physicians," it affirmed that portion of the award in July 2015.¹⁰⁰

“ Other courts, however, have allowed state AGs, often acting through state-retained contingency fee lawyers, to use UDAP laws to establish an alternative regulatory regime that competes with the FDA's authority. ”

MULTI-STATE PRESCRIPTION DRUG MARKETING SETTLEMENTS GO BEYOND FDA REQUIREMENTS

Some courts have found that their state UDAP laws do not apply to pharmaceutical marketing practices because they are already closely regulated by the FDA.¹⁰¹ Other courts, however, have allowed state AGs, often acting through state-retained contingency fee lawyers, to use UDAP laws to establish an alternative regulatory regime that competes with the FDA's authority.

“ Through the settlement agreement, AGs effectively switched a voluntary review procedure to a mandatory one, which is power the FDA does not have due to potential First Amendment violations. ”

MERCK VIOXX SETTLEMENT AND STATE AG’S NEW REGULATORY POWERS

In the \$58 million multi-state AG Vioxx settlement with Merck in 2008, state AGs afforded themselves enforcement powers in the FDA’s regulatory realm and imposed new additional restrictions and obligations over the future marketing of Merck’s products.¹⁰² Under the agreement, Merck agreed to both refrain from making promotional claims, including oral statements by its sales representatives, that are false, misleading, or deceptive, and to comply with the Federal Food, Drug, and Cosmetic Act as well as FDA requirements in connection with advertising and promotion.¹⁰³ By agreeing to such terms, Merck effectively granted these state AGs the power to enforce violations of FDA regulations.

The settlement also imposed new regulatory obligations on Merck. Merck agreed to “submit all new [Direct to Consumer (DTC)] television advertising campaigns for any Merck Product to FDA for pre-review, wait until Merck receives a response from FDA prior to running the advertising campaign, and to modify such advertising consistent with any written comments received from FDA.”¹⁰⁴ The agreement prevents Merck from running any DTC television ads until it receives a response from the FDA, no matter how much time passes after submission.¹⁰⁵

Through the settlement agreement, AGs effectively switched a voluntary review procedure to a mandatory one, which is power the FDA does not have due to potential First Amendment violations.¹⁰⁶

OFF-LABEL PROMOTION AND THE EXPANDED ROLE OF STATE AGS IN THE PFIZER CELEBRIX AND BEXTRA AND ABBOTT DEPAKOTE SETTLEMENTS

State AGs have also sought to expand their role in the regulation and restriction of off-label promotion. In the \$60 million multi-state settlement with Pfizer for the alleged deceptive marketing of Celebrix and Bextra in 2008, the state AGs placed several restrictions on off-label promotion.¹⁰⁷ The agreement prevented Pfizer from distributing samples with the intent to encourage off-label prescribing and from providing incentives to sales staff to increase off-label prescribing.¹⁰⁸ It barred Pfizer from disseminating information on an off-label use when the FDA rejected that off-label use, unless Pfizer clearly disclosed the FDA’s reasoning for rejecting it.¹⁰⁹ The agreement also prohibited Pfizer from distributing articles and studies from scientific or medical journals (“reprints”) discussing off-label uses in a promotional manner.¹¹⁰ It also required that materials used to respond to an unsolicited request by a physician about an off-label use be considered by experts to be scientifically sound, accompanied by a comprehensive

bibliography, and, if applicable, include a representative publication that reaches a contrary or different conclusion regarding the off-label use.¹¹¹

States became more entangled with federal regulation of pharmaceutical marketing when AGs entered a \$100 million settlement with Abbott regarding Depokote in 2012.¹¹² This agreement specifically prohibited Abbott from promoting Depakote for off-label uses.¹¹³ It provided specific guidelines on how Abbott could respond to an unsolicited request by a physician about an off-label use.¹¹⁴ Sales personnel could only respond to the physician by informing them of the presence or absence of published studies concerning the off-label topic or acknowledging whether the topic is an area of research, and by offering to request on behalf of the physician that medical information be sent out as follow-up.¹¹⁵ The agreement restricted the type of medical information that Abbott could develop and use for these responses, and sales personnel were prevented from characterizing, describing, identifying, naming, or offering any opinions about or summarizing any such off-label information.¹¹⁶ In addition, reprints containing information on an off-label use could only be sent out by scientifically trained personnel.¹¹⁷

It appears unlikely that the FDA could enforce some of these restrictions on off-label promotion. In 2012, the U.S. Court of Appeals for the Second Circuit held in *United States v. Caronia* that the First Amendment prohibits the government

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from prosecuting a drug manufacturer or individual solely on the basis of truthful speech.¹¹⁸ The FDA subsequently attempted to limit the applicability of *Caronia* to the particular facts and circumstances of that case, but recently, a federal district court in New York held that the First Amendment precludes the government from using the Federal Food, Drug, and Cosmetic Act to prohibit and criminalize truthful, non-misleading off-label speech.¹¹⁹ The court rejected the FDA’s attempts to “marginalize the holding” in *Caronia*, and it declined to limit *Caronia*’s holding to only reactive statements made by non-sales personnel.¹²⁰ It was the court’s “considered and firm view” that the FDA may not bring a misbranding action based on truthful non-misleading promotional speech alone.¹²¹

With these multi-state UDAP settlement agreements, state AGs are expanding their enforcement powers into the FDA's realm as well as creating entirely new regulatory demands on pharmaceutical manufacturers that go beyond the scope of the FDA's authority and may violate the First Amendment.

LOCAL ENFORCEMENT ACTIONS AGAINST PHARMACEUTICAL COMPANIES

Pharmaceutical companies have also had to respond to similar off-label marketing UDAP actions brought by local county district attorneys and city attorneys.

In May 2014, the Orange County, California district attorney and the Santa Clara County district attorney joined forces with contingency fee lawyers to bring a UDAP action on behalf of their residents against the major manufacturers of opioid painkillers such as OxyContin and Percocet.¹²² The complaint blames the manufacturers' "aggressive marketing" for all the problems associated with the "epidemic" of painkiller addictions, including the increased use of heroin, and sought civil penalties, restitution, and injunctive relief.¹²³ It alleges that the manufacturers engaged in an "intensive marketing" scheme to misrepresent the off-label benefits of using opioids for common non-cancer chronic pain like back pain, arthritis, and headaches.¹²⁴ The complaint claims that the manufacturers "deprived California patients and their doctors of the ability to make informed medical decisions and, instead caused important, sometimes life-or-death decisions to be made based not on science, but on hype."¹²⁵

As with the other pharmaceutical cases discussed above, the complaint references FDA warning letters as support for its marketing allegations.¹²⁶ Weeks after the California case was filed, the city of Chicago, using some of the same contingency fee lawyers, brought a similar action against the manufacturers.¹²⁷

In the California case, the Orange County Superior Court Judge Robert J. Moss granted the manufacturers' motion to stay the case pending the FDA inquiry and dismissed the case without prejudice in August 2015.¹²⁸ The judge found that "[t]his action could lead to inconsistencies with the FDA's findings, inconsistencies among the states, a lack of uniformity, and a potential chilling effect on the prescription of these drugs for those who need them most."¹²⁹ The judge recognized that the determinations the court would need to make, in order to rule on whether the marketing was improper, falls within the purview of the FDA, and he did not want to involve the court at this point "in an area which is best left to agencies such as the FDA who are designed to address such issues."¹³⁰

Nevertheless, the Chicago case is ongoing. Although a federal court declined to disqualify Cohen Milstein Sellers & Toll PLLC from representing Chicago in December 2014,¹³¹ the court later dismissed the case. In a May 2015 ruling, Judge Jorge L. Alonso found that the FDA's authority to regulate opioid marketing did not preclude the lawsuit, but that the city had not provided enough details supporting its consumer

fraud allegations, such as a Chicago doctor or consumer who was influenced by a misrepresentation.¹³² The city filed a 300-page amended complaint in November 2015, keeping the suit alive.¹³³

PENNSYLVANIA: AG USES UDAP TO TARGET NURSING HOME STAFFING

AG use of UDAPs to regulate already-regulated industries extends to other businesses that comply with state and federal regulations. As noted earlier, in Pennsylvania, then-AG Kathleen Kane bought an action against a group of skilled nursing facilities (SNF) over staffing levels under the Pennsylvania Unfair Trade Practices and Consumer Protection Law (UTPCPL).¹³⁴ She did so at the prompting of Cohen Milstein, which used the state's broad subpoena power to require the facilities to produce information on the number of residents and staffing of each facility¹³⁵ even before filing suit on June 30, 2015.¹³⁶ Targets of the litigation include a half dozen or more nursing home chains representing about 50% of the licensed beds in for-profit nursing homes in Pennsylvania.¹³⁷ The Commonwealth's complaint seeks a civil penalty for each violation of the UTPCPL and, when the alleged violations involve individuals over 65 years of age, the civil fine rises from \$1,000 per violation to \$3,000 per violation.¹³⁸

“ AG use of UDAPs to regulate already-regulated industries extends to other businesses that comply with state and federal regulations. ”

The Pennsylvania's Department of Health (PA DOH) regulates staffing in SNFs.¹³⁹ The PA DOH has adopted specific regulations governing nursing staff levels and the quality of care at SNFs. PA DOH regularly inspects SNFs to ensure that staffing regulations and care requirements are being met and is vested with the exclusive authority to bring actions or raise staffing levels where necessary.¹⁴⁰ Pennsylvania law authorizes PA DOH to bring enforcement actions in the name of the Commonwealth for an injunction or other process restraining or prohibiting a healthcare provider from engaging in an activity in violation of the provisions of the Act or its implementing regulations.¹⁴¹

In addition, PA DOH is the state agency responsible for ensuring that SNFs in Pennsylvania meet federal conditions for participation in both the Medicare and Medicaid programs.¹⁴² As part of this responsibility, PA DOH inspects each SNF at least annually and in response to complaints, and then must certify to the federal Centers for Medicare and Medicaid Services (CMS) that each SNF complies with the federal conditions for participation, including meeting federal staffing requirements.¹⁴³

The nursing facilities recently argued in Pennsylvania Commonwealth Court, an intermediate appellate court, that AG Kane overstepped her authority by “attempt[ing] to impose new and unapproved staffing standards without notice and comment,” and they challenged the AG’s authority to contract out enforcement power to private lawyers.¹⁴⁴ In seeking a preliminary injunction against the state, the facilities stated that they expected the AG and her outside counsel to seize upon general statements the facilities made about providing for the needs of nursing home residents to allege that they engaged in deceptive marketing practices under the UTPCPL.¹⁴⁵ The facilities also stated that they anticipate the AG will then attempt to use the UTPCPL to establish a new minimum staffing requirement in Pennsylvania of 2.8 to 3.2 hours of nursing aide staff per patient per day, which conflicts with PA DOH’s minimum staffing requirement of 2.7 hours of nursing care per resident per day.¹⁴⁶

In January 2016, however, the Commonwealth Court ruled that the Pennsylvania AG’s office could use the state’s UDAP law to address advertisements or other representations about nursing home staffing levels, “whether in accord with those required by statute or regulation or not.”¹⁴⁷

Reform Options

- In states lacking a provision recognizing the interaction between UDAP enforcement and activities already regulated by government agencies, adopt a law similar to most other states. This law might clarify that the UDAP law does not apply to “acts or practices permitted under laws of this State or the United States or under rules, regulations, or decisions interpreting such laws.”
- In states that have enacted such provisions, but where courts have interpreted them in a manner inconsistent with their purpose, amend the law as needed to preclude UDAP liability when the conduct at issue was permitted by government regulators or the product’s labeling or marketing was specifically approved by an agency charged with safeguarding the public.
- Courts should find that warning letters and other informal correspondence issued by staff at regulatory agencies without any hearing or right to appeal are more prejudicial than probative in UDAP litigation. Nor do they fall within a recognized exception to the hearsay rule. While such letters should already be inadmissible in court under existing evidentiary rules, state legislatures may consider clarifying the law.

Unpredictable & Excessive Civil Penalties

State attorneys general and their hired outside counsel typically request the maximum civil penalty authorized for UDAP violations. They often allege that every product sold, prescription filled, letter sent, or advertisement published is a separate violation. The result is a wholly unpredictable system with wildly varying penalties that raise significant due process concerns.

UDAP laws provide a means for state AGs to protect the rights of consumers by seeking injunctions to stop unfair or deceptive business practices before they cause harm and, where consumers have lost money, obtain restitution for them. These laws also authorize AGs to request that a court punish companies that have violated the UDAP law and deter others from engaging in similar conduct by imposing civil penalties. These civil penalties can reach astronomical levels and lack proportionality to the business's conduct or the harm to consumers.

Typically, all that an AG needs to show to establish a UDAP violation is that a business practice had the *tendency* to deceive or was capable of misleading someone.¹⁴⁸ A violation of the law occurs even if the business did not intend to deceive the public, consumers were not misled, and there was no actual loss.

Most UDAP laws allow the AG to seek, and the court to impose, a civil penalty for *any* violation of the act. About 20 state laws require evidence that a business knowingly, willfully, or intentionally engaged in a deceptive practice before imposing civil penalties,¹⁴⁹ though in practice, this culpability requirement is often given little consideration.¹⁵⁰

Depending on the state, civil penalties range from up to \$1,000 to up to \$50,000 per violation, with only a handful of states set at the lower end of the spectrum.¹⁵¹ Most states have maximum civil penalties in the range of \$2,500 to \$5,000 per violation. Almost half of the states have maximum penalties set at \$10,000,¹⁵² or more.¹⁵³ In addition, some states provide for additional civil penalties when a violation involves individuals who are elderly or disabled,¹⁵⁴ and some provide for additional penalties for repeat offenders.¹⁵⁵ Most UDAP laws provide no guidance to judges as to when

“ Most UDAP laws provide no guidance to judges as to when a civil penalty should be on the smaller or larger end of the permissible range. AGs, and the contingency fee lawyers they hire to bring such suits, often indiscriminately seek the maximum fine permitted under the law. ”

a civil penalty should be on the smaller or larger end of the permissible range. AGs, and the contingency fee lawyers they hire to bring such suits, often indiscriminately seek the maximum fine permitted under the law.

The arbitrariness of the amount of the civil penalty is compounded by how courts count the number of violations. AGs often seek “per violation” civil penalties based on every prescription filled, letter sent, product sold, or advertisement published or aired for the longest period allowed under the statute of limitations. As a result, businesses are subject to extraordinary civil penalties for a single action even when the conduct did not mislead anyone or cause an economic loss.

These problems do not arise under the Federal Trade Commission Act, the model for many state UDAP laws. Federal law authorizes the FTC to bring an action against a business that has engaged in deceptive practices and obtain a cease-and-desist order. The FTC can also require businesses that violate federal law to provide consumers with refunds, pay damages, or provide other consumer redress.¹⁵⁶ For example, a company accused of selling bogus

weight loss pills and using fake celebrity endorsements recently agreed to pay \$43 million to settle the FTC’s claims, which will go into a consumer redress fund.¹⁵⁷

In addition, the FTC can seek civil penalties of up to \$16,000 per violation when a business violates a consent agreement (under which it agreed, without admitting liability, to stop a practice of concern to the Commission) or continues a practice after the Commission finds it is deceptive and issues a cease-and-desist order.¹⁵⁸

The Commission may also seek civil penalties from businesses that have not entered a consent agreement or received a cease-and-desist order if the FTC first provides that business with a copy of the Commission determination in a similar case finding the act or practice unfair or deceptive.¹⁵⁹ The public policy underlying this process is a recognition that “unfair” and “deceptive” are broad, vague terms and that it is improper to punish a business without first giving it notice that its conduct violates the law. Civil penalties are reserved for situations in which the violator had “actual knowledge that such act or practice is unfair or deceptive and is unlawful.”¹⁶⁰

There is no such process before a state AG decides to bring an action under state UDAP laws. Rather, in nearly every state, the AG can immediately seek civil penalties, without first providing notice of a violation¹⁶¹ or seeking an injunction or other relief for consumers.¹⁶² And, as discussed earlier, when the state litigates through a contingency fee arrangement, the private lawyers representing the state have an incentive to seek the maximum conceivable penalty in every case, no matter how excessive.

Due to the lack of notice as to the legality of conduct under UDAPs, the unpredictability of the potential penalty, and the lack of proportionality in many cases between the size of the fine and the conduct or harm, these civil penalties raise serious constitutional concerns under the Due Process Clause and Excessive Fines Clauses of the U.S. Constitution and similar state constitutional safeguards.¹⁶³

Recent Examples

SOUTH CAROLINA: STATE SUPREME COURT IMPOSES MULTI-MILLION DOLLAR FINE EVEN AS IT ACKNOWLEDGES LACK OF DECEPTION OR HARM TO PUBLIC

As previously noted, in South Carolina, then-AG Henry McMaster brought an action under South Carolina Unfair Trade Practices Act (SCUTPA) against Janssen for its marketing of Risperdal.¹⁶⁴ The action provides an example of the arbitrary nature in how civil penalties can be calculated, and it illustrates the level of exposure companies can face when the aggregation of “per violation” is combined with a lower standard of proof. Under SCUTPA, the AG is authorized to seek up to \$5,000 per violation

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upon a showing that the party knew or should have known that the conduct was unlawful.¹⁶⁵ The AG is not required to prove that the company’s statements were made with an intent to deceive, caused anyone any injury, or that anyone relied on these statements to impose a civil penalty, but only that the statements at issue have a “tendency to deceive.”¹⁶⁶

The state, litigating through private contingency fee lawyers, made two distinct claims under SCUTPA: (1) the Risperdal labeling itself was unfair and misleading because it did not include sufficient information on the risks associated with the drug; and (2) the “Dear Doctor” letter sent by the company to doctors about the drug was misleading. In making these claims, the AG relied on the previously discussed April 2004 FDA warning letter, which concluded that the “Dear Doctor” letter did not properly disclose the risks of hyperglycemia and diabetes associated with the drug.¹⁶⁷ In response, the manufacturer sent a corrective letter to doctors acknowledging the omission.¹⁶⁸

The state argued, and the trial court agreed, that the distribution to physicians of each sample box containing the alleged deceptive labeling, each “Dear Doctor” letter, and each follow-up sales call after the “Dear Doctor” letter constituted a separate SCUPTA violation.¹⁶⁹ The trial court imposed a \$300 civil penalty for each of 509,499 Risperdal sample boxes distributed in the state between 1998 and the date the lawsuit was filed on April 23, 2007 (\$152.8 million).¹⁷⁰ It also imposed a \$4,000 civil penalty for each of 7,184 “Dear Doctor” letters sent to physicians in the state (\$28.7 million) and each of 36,372 follow-up sales calls made to doctors (\$145.5 million).¹⁷¹ The total civil penalty was reportedly the largest imposed under SCUPTA in state history.¹⁷² As the South Carolina Chamber said in its *amicus* brief filed with the state high court,

“The South Carolina Supreme Court found the ‘per box’ and ‘per sales call’ civil penalty amounts excessive. It reduced these fines from \$300 to \$100 and \$4,000 to \$2,000, respectively, but offered little explanation for why its substituted amounts were reasonable, but the trial court’s amounts were not.”

such subjective penalties do not “merely give rise to uncertainty for business[es], it demonstrates an overt hostility toward business,” which could threaten the “State’s efforts to recruit and retain businesses.”¹⁷³ But the court discounted any chilling effect the verdict could have on businesses.¹⁷⁴

The South Carolina Supreme Court found the “per box” and “per sales call” civil penalty amounts excessive. It reduced these fines from \$300 to \$100 and \$4,000 to \$2,000, respectively, but offered little explanation for why its substituted amounts were reasonable, but the trial court’s amounts were not.¹⁷⁵ The court did not reduce the \$4,000 penalty for each “Dear Doctor” letter, calling the question of whether this fine was excessive a “close” one.¹⁷⁶

The South Carolina Supreme Court directed trial courts to consider a list of non-exclusive factors when assessing civil penalties under SCUPTA in the future. These factors include: (1) the degree of culpability and good or bad faith of the defendant; (2) the duration of the defendant’s unlawful conduct; (3) active concealment of information by the defendant; (4) the defendant’s awareness of the unfair or deceptive nature of their conduct; (5) prior similar conduct by the defendant; (6) the defendant’s ability to pay; (7) the deterrence value of the assessed penalties; and (8) the actual impact or injury to the public resulting from the defendant’s conduct.¹⁷⁷

“ [T]he South Carolina Supreme Court reduced the total combined civil penalty from \$327 million to \$124 million, declaring that by doing so it had resolved any due process concerns and the penalties were not excessive under the prohibition of excessive fines under the Eighth Amendment to the U.S. Constitution. ”

The court did not discuss in depth how it weighed these factors to arrive at what it deemed to be a non-excessive fine. It found that the manufacturer, in an effort to increase sales, had given misleading information to doctors, warranting civil penalties.¹⁷⁸ But the court acknowledged that the manufacturer’s conduct “likely had little impact on the community of prescribing physicians.”¹⁷⁹ The court recognized an “absence of significant actual harm” to the public.¹⁸⁰ It also found the trial court improperly included old sales that were outside the statute of limitations.¹⁸¹

As a result, the South Carolina Supreme Court reduced the total combined civil penalty from \$327 million to \$124 million, declaring that by doing so it had resolved any due process concerns and the penalties were not excessive under the prohibition of excessive fines under the Eighth Amendment to the U.S. Constitution.¹⁸² The civil penalty imposed by South Carolina, however, was 25 times greater than the average state award under the settlement agreement with 36 states and the District of Columbia to resolve their UDAP claims regarding Risperdal marketing.¹⁸³ The U.S. Supreme Court denied a petition for review of the \$124 million fine in January 2016.

MISSISSIPPI: FEDERAL COURT CONCERNED WITH STATE’S “SLASH AND BURN” TACTICS

In a similar action, Mississippi AG Jim Hood, working with plaintiffs’ law firms (one of which reportedly donated \$75,000 to his campaign),¹⁸⁴ filed an action against Eli Lilly related to its marketing of Zyprexa, a drug that is in the same class as Risperdal. While the FDA approved Zyprexa for treating serious psychiatric disorders, such as schizophrenia and bipolar disorder, the lawsuit alleged the company marketed it for unapproved uses and that it did not fully disclose potential risks, such as weight gain and diabetes. AG Hood’s lawsuit was one of 40 brought by AGs across the country. Nearly all other states had settled their claims with the drug maker by 2009, but Mississippi opted out. Its private lawyers instead sought millions of dollars in “per violation” civil penalties.

The Mississippi Consumer Protection Act (MCPA) authorizes “a civil penalty in a sum not to exceed Ten Thousand Dollars (\$10,000)” for each knowing and willful violation.¹⁸⁵ AG Hood requested that the court apply this maximum amount to each of almost one million estimated Zyprexa prescriptions in Mississippi.¹⁸⁶ Attorneys for the state took the position that Mississippi was entitled to this amount without the need to show proof of reliance or causation, and irrespective of any costs or damages borne by the state.¹⁸⁷

In December 2009, Judge Jack B. Weinstein of the U.S. District Court for the Eastern District of New York dismissed Mississippi’s claim for statutory penalties under the MCPA, as well as all but one of the state’s other claims. Judge Weinstein found that in order to appropriately assess a civil penalty, he would need more information about each prescription filled, such as whether it was for an approved or off-label use, whether the patient benefited from the medicine, and whether the patient experienced any of the potential side effects at issue.¹⁸⁸ The state, however, had not offered such individual information, making it impossible for the court to fairly exercise its discretion to impose appropriate

penalties. This type of assessment, Judge Weinstein added, would be beyond the resources of the court, given the individualized inquiry needed for hundreds of thousands of claimed violations.¹⁸⁹

On the other hand, Judge Weinstein found that Lilly had “created a product with substantial benefits that even now – after many years of litigation, research, testing and controversy – is still favored by many physicians and patients in Mississippi and elsewhere for some of the most serious psychological conditions that affect millions of people worldwide.”¹⁹⁰

Judge Weinstein also recognized “serious constitutional questions” with the scale of recovery sought by Mississippi.¹⁹¹ He found that “Mississippi’s request for statutory penalties on a per-violation basis, in addition to actual damages sought, would result in a multibillion dollar cumulative penalty grossly disproportionate to both the injury Mississippi had suffered and the seriousness of Lilly’s alleged misconduct.”¹⁹² These types of claims, which aggregate civil penalties on a per violation basis, “could result in serious harm or bankruptcy for this defendant and the pharmaceutical industry generally.”¹⁹³ Judge Weinstein concluded:

“These types of claims, which aggregate civil penalties on a per violation basis, ‘could result in serious harm or bankruptcy for this defendant and the pharmaceutical industry generally.’”

“ Constitutional, statutory, and common law rights of those injured to seek relief from the courts must be recognized. But courts cannot be used as an engine of an industry’s unnecessary destruction. ”

For the legal system to be used for this slash-and-burn style of litigation would arguably constitute an abuse of the legal process. Constitutional, statutory, and common law rights of those injured to seek relief from the courts must be recognized. But courts cannot be used as an engine of an industry’s unnecessary destruction.¹⁹⁴

Just two months after Judge Weinstein’s ruling, Mississippi agreed to an \$18.5 million settlement, an amount that was far less than it had sought.¹⁹⁵

The “Pile-On Effect”

It is commonplace for businesses to face similar UDAP enforcement actions from multiple states or a coordinated multi-state AG action. Consumer class actions, sometimes brought by the same contingency fee lawyers who sued on behalf of state AGs, may seek treble damages and attorneys’ fees. Individual lawsuits stemming from the same conduct may seek actual damages,

statutory damages, and punitive damages. Businesses may also face claims brought by the federal government. The potential liability exposure for a single act, practice, or alleged misrepresentation is staggering.

For example, in the litigation alleging Lilly improperly marketed Zyprexa, the pharmaceutical maker agreed to a \$62 million multi-state settlement with 33 state AGs to resolve UDAP claims.¹⁹⁶ It then settled individually with the state AGs of Arkansas, Connecticut, Idaho, Mississippi, Montana, New Mexico, South Carolina, Utah, and West Virginia for roughly \$196 million.¹⁹⁷ Lilly also settled the DOJ’s off-label marketing allegations for \$1.415 billion,¹⁹⁸ and settled roughly 26,000 individual products liability suits for \$1.2 billion.¹⁹⁹ Lilly also faced a class action brought on behalf of third-party payor institutional plaintiffs, including pension funds, labor unions, and insurance companies that made outlays for Zyprexa prescriptions, as well as several shareholder derivative actions.²⁰⁰

This form of cumulative litigation is not isolated to the pharmaceutical industry. Toyota faced a similar set of lawsuits in the unintended acceleration litigation. Toyota agreed to a \$29 million settlement with 30 state AGs to resolve UDAP claims,²⁰¹ plus another \$16 million to settle UDAP claims brought by the Orange County, California District Attorney.²⁰² The issue also generated a consumer class action lawsuit seeking economic losses on behalf of all vehicle owners, which Toyota settled for an estimated \$1.1 billion²⁰³ (and which delivered a little as \$20.91 to some Toyota owners, while 85 plaintiffs’ attorneys involved collected \$227 million in fees and costs).²⁰⁴ In addition, the automaker paid a \$1.2 billion penalty to the

federal government,²⁰⁵ settled a shareholder class action for \$25.5 million,²⁰⁶ and settled around 340 personal injury/wrongful death suits for an undisclosed sum.²⁰⁷

Courts have recognized that punishing a business repeatedly for the same conduct raises significant constitutional concerns.²⁰⁸ State legislatures should address arbitrary and repetitive civil penalties imposed under state UDAP laws.

Reform Options

- Authorize civil penalties in instances in which a court finds that a business willfully engaged in an unfair or deceptive practice.
 - Place an aggregate limit on “per violation” civil penalties, such as \$5 million for “any related series of violations.” Federal laws providing for civil penalties include such maximum levels.²⁰⁹ Alternatively, provide a cap linked to the actual harm to consumers or profit received by the business as a result of the violation. For example, a state law might provide that for any related series of violations, a civil penalty shall not exceed the greater of: (1) three times the actual loss caused by the violation; (2) three times the profit gained as a result of the violation; or (3) \$5 million.²¹⁰
 - Provide that unfair or deceptive conduct that could harm consumers, but has not caused actual harm, is subject to an injunction to stop the practice and a lower civil penalty. For example, a state that ordinarily provides for a civil penalty of \$10,000 per violation might provide that a prohibited practice that did not result in significant harm to the public is subject to an injunction and a civil penalty not to exceed \$1,000 per violation, but no more than \$1 million for any related series of violations.
- Provide courts with factors to guide them in determining a fair and reasonable civil penalty. Although penalty factors are common in laws authorizing civil penalties or regulations implementing those laws,²¹¹ few UDAP statutes include them.²¹² Where a statute or regulation does not provide such guidance, some courts have developed penalty factors.²¹³ For example, a state law might provide that when determining the size of an appropriate civil penalty, a court shall consider:
 - 1) the degree of culpability and good or bad faith;
 - 2) the actual impact or injury to the public resulting from the conduct;
 - 3) the sophistication or level of knowledge of the parties;
 - 4) the duration of the unlawful conduct;
 - 5) any corrective action taken;
 - 6) whether the person actively concealed the unlawful conduct;
 - 7) whether the person engaged in prior similar conduct;
 - 8) the deterrent value of the penalty;
 - 9) any other liability imposed as a result of the same course of conduct; and
 - 10) the potential for undue adverse economic impacts.

Spending of Settlement Money on Pet Projects and Politically Popular Groups

One might think that money recovered through UDAP settlements would go to the state treasury, providing a benefit for taxpayers. It would also be reasonable to assume that the state uses the settlement funds to help consumers who have been injured by the deceptive practices at issue or, at the very least, finance programs tied to the conduct at issue. Most people would be surprised to learn that state officials sometimes use money collected as a result of UDAP enforcement actions for purposes unrelated to the litigation.

Many state laws either do not expressly address the use of money recovered through UDAP litigation or the creation of consumer funds, allowing AGs and other officials wide discretion as to how they spend millions of dollars of state funds. Some AGs have used this money to fund their own pet projects, favorite nonprofits or causes, or for self-promotion. It is not out of the ordinary for an AG to recover funds through a consumer protection enforcement action and then use that money for purposes that have little, if anything, to do with addressing the type of conduct that spurred the lawsuit or any harm that occurred.

At its core, this practice calls into question whether state officials are neutrally exercising law enforcement power to address a real harm to consumers, or targeting businesses perceived as deep pockets for other reasons. The practice also raises constitutional questions because it circumvents the legislative appropriation process, proper oversight, and accountability.

As this section shows, these types of questionable practices are widespread and growing across party lines. In a time of tightening state budgets, the incentive for misuse of funds continues to rise.

“ At its core, this practice calls into question whether state officials are neutrally exercising law enforcement power to address a real harm to consumers, or targeting businesses perceived as deep pockets for other reasons. ”

Recent Examples

ARKANSAS: YOGURT ADVERTISING SETTLEMENT TO FEED THE HUNGRY, PHARMACEUTICAL SETTLEMENTS FOR POLICE TRAINING FACILITY AND OFFICE PROMOTION

In December 2010, Arkansas AG Dustin McDaniel was among a group of state AGs settling a lawsuit with The Dannon Company, Inc. alleging the company violated state UDAP laws in advertising Activia and DanActive products. Arkansas’s share of the \$21 million settlement, \$425,000, was divided among three Arkansas hunger-relief organizations, the Arkansas Foodbank, Arkansas Hunger Relief Alliance, and Arkansas Rice Depot.²¹⁴ AG McDaniel’s action was widely criticized. Lieutenant Governor Mark Darr commented, “great charity, great thing to do, but I question the ethics on that because I think that if I were to do that it would look like I was trying to buy some votes.”²¹⁵ Others noted that AG McDaniel’s wife served at the time on Foodbank’s Board of Directors.²¹⁶

In a separate instance in July 2011, McDaniel, a former police officer, announced that he would donate \$700,000 of settlement money his office received as a result of a multi-state AG UDAP action against two pharmaceutical makers to the Arkansas State Police Foundation.²¹⁷ Money received as a result of the lawsuit, which alleged the manufacturers violated drug manufacturing standards, would be used to build a new training facility at a police shooting range. The AG made the announcement through a five-minute video produced at an estimated cost of \$6,000 and aired at the annual Police Foundation awards luncheon.²¹⁸ McDaniel stated that he would rather donate the money to a good cause than “fill budget holes for legislators.”²¹⁹ Once again, there was no connection between the lawsuit and McDaniel’s allocation of the settlement money.

Due to public outcry, the office of the Arkansas AG announced a new internal policy on lawsuit settlement funds in October 2011,²²⁰ which the state legislature codified in August 2013.²²¹ It provides that whenever the state receives a portion of a settlement or judgment from an action to which the state is a party, the AG must distribute the money in the following manner: (1) payment to the Arkansas consumers or state agencies designed by a court order or settlement agreement; (2) payment to a state agency having a nexus to the underlying litigation; (3) payment of attorney’s fees to the State Treasury; or (4) payment into the AG’s “Consumer Education and Enforcement Account,” which can maintain no more than a

\$1 million balance. The law also requires the AG to provide quarterly financial reports to the Legislative Council as to all expenditures made pursuant to this law.

The new system may curtail but not stop such abuse. In 2012, after the AG's adoption of the policy but before its codification, McDaniel again came under fire for using proceeds from the state's Zyprexa settlement to fund an advertising campaign and website promoting his office's consumer protection activities, called "Got Your Back Arkansas." "I wish my office had millions at its disposal to run my campaign ads," commented Lt. Gov. Darr.²²²

Arkansas's new AG, Leslie Rutledge, has not distributed state money to outside organizations.²²³ She recently sent two thirds of a \$21.5 million settlement with Standard & Poor's to the state treasury, but did distribute approximately \$6 million of the recovery to state agencies for public safety and law enforcement purposes unrelated to the litigation.²²⁴

CALIFORNIA: UNINTENDED ACCELERATION SETTLEMENT TO ADDRESS GANG VIOLENCE

In California, County District Attorneys have the power to enforce the state's consumer laws. Orange County DA Tony Rackauckas brought a lawsuit against Toyota, claiming that Toyota's alleged concealment of safety issues related to its floor mats and "sticky" gas pedal issues violated the state's Unfair Competition Law and False Advertising Law. To pursue the action, the county hired plaintiffs' law firms Robinson Calcagnie

“ The settlement agreement provides that all of Toyota's payments will be made 'pursuant to wire transfer instructions provided to Toyota by the District Attorney's Outside Counsel.' ”

Unsurprisingly, the DA then came under fire from the Orange County Board of Supervisors, whose members were frustrated that none of the settlement funds came back to the county's discretionary budget.”

Robinson Shapiro Davis, Hagens Berman Sobal Shapiro LLP, and Girardi Keese, all of which had a role in a class action seeking economic losses from Toyota on behalf of owners²²⁵ (in which lawyers received fees totaling \$200 million plus \$27 million in costs and expenses,²²⁶ while some owners received a check for \$20.91).²²⁷

Toyota settled the county's lawsuit for \$16 million in 2013. Rackauckas said half of the settlement would fund county programs to address gang violence.²²⁸ Of the remaining \$8 million, \$4 million would pay for the costs of the lawsuit, including the fees of outside counsel, and \$4 million would remain with his office to "fight economic crime."²²⁹ The settlement agreement provides that all of Toyota's payments will be made "pursuant to wire transfer instructions provided to Toyota by the District Attorney's Outside Counsel."²³⁰

Unsurprisingly, the DA then came under fire from the Orange County Board of Supervisors, whose members were frustrated that none of the settlement funds came back to the county's discretionary budget.²³¹

KENTUCKY: VIOXX AND AVANDIA SETTLEMENTS FUND DRUG TREATMENT

In January 2014, Kentucky AG Jack Conway announced that more than \$32 million collected from settlements with two drug companies would be used to expand substance abuse treatment centers. The lawsuits, however, had nothing to do with substance abuse. They alleged that Merck Sharp & Dohme Corporation and GlaxoSmithKline had violated the Kentucky Consumer Protection Act by failing to disclose cardiovascular risks of Vioxx and Avandia, respectively.

At a news conference, AG Conway announced his plan to divide the settlement funds among a variety of drug treatment programs, including:

- \$19 million to start a grant program, KY Kids Recovery, to finance juvenile abuse treatment programs;
- \$6 million to administer the state's electronic prescription drug monitoring program;
- \$2.52 million for scholarships to seek treatment at the state's Recovery Kentucky Centers;
- \$1.5 million to the University of Kentucky to assist treatment providers;
- \$1 million to support drug programs for pregnant women;
- \$1 million for a school-based substance abuse screening tool with the state Department of Education;
- \$560,000 to help create 14 drug-free homes for people making the transition out of residential drug treatment programs;
- \$500,000 to complete construction of a treatment center in Ashland, Kentucky; and
- \$250,000 to create a database to evaluate the outcomes of juvenile treatment.

“ Senate President Stivers did not object to how the money was going to be used, but questioned the legality of the arrangement since he believed that Kentucky law requires depositing settlement money in the General Fund and appropriation by the legislature.”

Some members of the state legislature, including Senate President Robert Stivers, expressed concern that the funds from the settlement were not placed in the state’s General Fund.²³² Senate President Stivers did not object to how the money was going to be used, but questioned the legality of the arrangement since he believed that Kentucky law requires depositing settlement money in the General Fund and appropriation by the legislature.²³³

The Kentucky law appears to support the senator’s position. A state statute recognizes that the power to appropriate funds for public purposes is “solely within the purview of the legislative branch of government.”²³⁴ The statute explicitly states:

[W]henver the attorney general ... is a party to or has entered his appearance in, a legal action on behalf of the commonwealth of Kentucky ... and a disposition of that action has resulted in the recovery of funds or assets to be held in trust by the attorney general ... or by a person, organization, or entity created by the attorney general, or Commonwealth, through court action or otherwise, to administer the trust funds or assets, for charitable, eleemosynary, benevolent, educational, or similar

public purposes, those funds shall be deposited in the State Treasury and the funds or assets or disbursed by the Office of the Controller.²³⁵

The Kentucky law also provides for the recovery of reasonable costs of litigation by the Office of the Attorney General, after which “[a]ll remaining funds shall be deposited in the general fund surplus account.”²³⁶ Under that law, any expenditure from the surplus account must be appropriated by the General Assembly.²³⁷ Despite these clear statutory requirements, the AG’s allocation of the money received through the Vioxx settlement went unchallenged.

MAINE: AG CLAIMS SOLE DISCRETION IN ALLOCATING STATE’S SHARE OF \$1.375 BILLION SETTLEMENT

In February 2015, the U.S. Department of Justice announced a \$1.375 billion settlement on behalf of the federal government, 19 states, and the District of Columbia with Standard & Poors Financial Services LLC, along with its parent corporation McGraw Hill Financial, Inc., to resolve allegations involving how it issued ratings for residential mortgage-backed securities and collateralized debt obligations.²³⁸ Maine’s claims, brought under its UDAP law, gained the state a \$21.5 million share of the settlement, which AG

Janet Mills described as the largest ever one-time court settlement in the state's history.²³⁹ AG Mills announced that she planned to allocate the funds to consumer protection-related purposes in her sole discretion.²⁴⁰

Maine Governor Paul LePage challenged the AG's authority to unilaterally divvy out state funds, noting that the power to

appropriate revenue is constitutionally given to the legislature checked by the Executive.²⁴¹ He supported legislation that would have restricted the AG from spending public money received through UDAP settlements.²⁴² The bill was not enacted.²⁴³

MICHIGAN: MORTGAGE COMPANY SETTLEMENT TO FUND PARKS, THEN UNITED WAY

In 2009, Michigan AG Mike Cox came under fire when he announced that he would use \$500,000 of the state's settlement with Countrywide Financial Group to fund two Grand Rapids-area parks. While the bulk of the settlement, \$6.7 million of the \$9.9 million, would be distributed to 3,700 former Countrywide customers who would receive about \$1,800 each, some local and state leaders were furious. They felt the funds could have been better spent to help families who had lost their homes to foreclosure.

Cox suggested that park improvements would help stabilize the surrounding neighborhoods, providing some tie to the lawsuit. Democrats charged, however, that Cox decided to give the money to the parks after being approached by a major GOP donor who also heads fundraising for one of the county-owned parks.²⁴⁴ They also charged that Cox, who was considering a run for Governor, had distributed the money to further his political ambitions.²⁴⁵ As a result of the public criticism, Cox ultimately donated the settlement money to the Heart of West Michigan United Way rather than fund the parks.²⁴⁶ His rationale for donating the money to the United Way was that it is an "unimpeachable organization."²⁴⁷

“ In 2009, Michigan AG Mike Cox came under fire when he announced that he would use \$500,000 of the state's settlement with Countrywide Financial Group to fund two Grand Rapids-area parks. While the bulk of the settlement, \$6.7 million of the \$9.9 million, would be distributed to 3,700 former Countrywide customers who would receive about \$1,800 each, some local and state leaders were furious. ”

Soon after, State Representative Mark Meadows introduced legislation that would have required any settlement proceeds to be allocated out through the standard appropriations process, rather than by the AG.²⁴⁸ The bill sought to clarify a Michigan law that explicitly states: “All moneys received by the attorney general, for debts due, or penalties forfeited to the people of this state, shall be paid by him or her, immediately after receipt, into the state treasury.”²⁴⁹ But the statute also states that “any proceeds from a lawsuit settlement entered into by a state agency ... as the result of an action instituted on behalf of the state against a private individual or business ... shall be deposited into a restricted fund to be used as provided by law.”²⁵⁰

The legislation would have addressed the conflicting language in the statute that opened the door to the AG’s spending of money on parks by providing that settlement money deposited into a restricted fund would be used as provided by law after appropriation.²⁵¹ The bill would have also required the AG to provide a quarterly report to the legislature on case settlements and prohibited use of settlement proceeds to finance advertisements or public service messages from state officials or persons running for state office.²⁵² The bill did not advance.

“ *McGraw was also criticized for spending thousands of dollars of settlement money to publicize the activities of his office—conveniently during election years—and on trinkets such as key chains and bumper stickers bearing his name.* ”

WEST VIRGINIA: DRUG SETTLEMENT USED TO ESTABLISH PHARMACY SCHOOL, TREAT ALCOHOLISM, FUND NURSING PROGRAM, AND BUILD POLICE FITNESS CENTER

Five-term West Virginia AG Darrell McGraw was well known and heavily criticized for his frequent use of private personal injury law firms and using settlement money collected on behalf of the public to fund his own pet project.²⁵³ McGraw was also criticized for spending thousands of dollars of settlement money to publicize the activities of his office—conveniently during election years—and on trinkets such as key chains and bumper stickers bearing his name.²⁵⁴

These types of practices ultimately ended up causing a roughly \$3.1 million shortfall in the state's Medicaid budget.²⁵⁵ The shortfall was a result of an \$850,000 settlement with Dey Inc. for its alleged marketing scheme that resulted in inflated reimbursement values for certain drugs, and a \$10 million settlement with Purdue Pharma for its alleged misrepresentations about the addictive capabilities of the painkiller OxyContin.²⁵⁶ In both of the underlying lawsuits, the AG claimed harm to the state Medicaid program.²⁵⁷

In the Dey settlement, the AG gave the bulk of the money to the Public Employees Insurance Agency and retained \$100,000 of the settlement for his office's consumer protection fund.²⁵⁸ The private attorneys hired by McGraw made \$250,000.²⁵⁹ In the Purdue settlement, the private attorneys hired by McGraw, who also happened to donate to McGraw's election campaigns, earned more than \$3.3 million.²⁶⁰ McGraw disbursed the remaining funds to various charitable causes of his choosing, including \$500,000 to the University of Charleston's pharmacy school,²⁶¹ \$30,000 to a Braxton County transition home for recovering alcoholics and substance abusers,²⁶² \$130,000 for a nursing program run by the wife of the State Senate president,²⁶³ and an unknown amount to help pay for a 12,000-foot fitness training center for West Virginia State Police Academy center.²⁶⁴ The state agencies in whose name McGraw sued received virtually none of the settlement, and the federal government, which funds a substantial portion of the state's Medicaid program, received nothing from both of these settlements.²⁶⁵

“The state agencies in whose name McGraw sued received virtually none of the settlement, and the federal government, which funds a substantial portion of the state's Medicaid program, received nothing from both of these settlements.”

In response, the U.S. Department of Health and Human Services (HHS) withheld from West Virginia's Department of Health and Human Resources \$2,732,968 for the Purdue settlement and \$447,000 for the Dey settlement.²⁶⁶ HHS claimed it was owed this amount since West Virginia did not reimburse HHS for its share in the Medicaid overpayments or inform HHS about these settlements.²⁶⁷ McGraw filed suit against HHS, but the U.S. Court of Appeals for the Fourth Circuit held in the *Dey* case that a “straightforward application of the Medicaid Act” shows that HHS had the right to withhold the settlement amount in Medicaid funds from the state.²⁶⁸

Following this controversy, McGraw ended up losing his reelection bid in 2012. AG Patrick Morrisey, who took office after defeating McGraw, instituted a number of reforms, including a competitive bidding process and caps on contingency fees for outside attorneys.²⁶⁹ He has also worked with the governor and legislature to transfer settlement money from his office to the state's general fund when the amount surpassed what was needed to operate the consumer protection division.²⁷⁰ For example, in 2013, the West Virginia legislature, with the support of AG Morrisey, reallocated \$7.5 million of the unappropriated surplus balance in the Consumer Protection Recovery Fund to the State Fund, General Revenue.²⁷¹

AG Morrisey does not spend money from the Consumer Protection Recovery Fund on outside organizations or pet projects. For example, West Virginia's \$20 million settlement with GSK related to Avandia marketing was distributed to the Public Employees Insurance Agency (\$10.6 million), the state Medicaid program (\$3.7 million), the AG's consumer protection fund (\$3.1 million), and the contingency fee lawyers hired by his predecessor who handled the case (\$4.6 million).²⁷²

Reform Options

There are several alternatives for addressing the questionable use of money received as a result of UDAP settlements and judgments by state officials.

- Provide that all funds received as a result of UDAP settlements or judgments, aside from money received for restitution of consumers or state agencies, must be deposited in the state's general fund. Several states, such as Florida, Iowa, Louisiana, Nevada, and Virginia, take this approach.²⁷³
 - Before depositing the money in the general fund, the law could also authorize the AG to use funds received as a result of UDAP settlements or judgments to reimburse documented, reasonable litigation expenses associated with that lawsuit, including expert witness fees, copying of documents, and transcripts.
 - Once deposited in the general fund, such funds would be allocated through the ordinary legislative appropriation process. This approach ensures that taxpayers receive the full benefit of any recovery.

- Permit the AG to retain a portion of UDAP settlements and judgments in a fund used exclusively to support the office’s consumer education and enforcement activities.
 - Subject the fund to a maximum balance after which any additional funds go to the state’s general fund. New Hampshire recently adopted this approach.²⁷⁴ New Hampshire requires that all funds recovered by the AG to be deposited in the consumer protection escrow account up to \$5 million with any excess funds to be deposited into the state’s general fund.²⁷⁵
 - This approach may be appropriate in states that already have such a fund in place to assist in financing the AG’s consumer protection efforts and ensure that settlement money is not spent on unrelated activities. The cap on the fund would ensure that taxpayers share the benefit when a state enters an extraordinary settlement or judgment and that large sums are not withheld from the legislative appropriation.
- Bar allocation of state recovery from UDAP settlements and judgments to outside organizations. Such a provision would eliminate the concerns that arise when state AGs and other officials give away money recovered as a result of litigation to politically popular causes, projects, and organizations.
- Permit the AG to distribute funds from UDAP settlements and judgments to a state agency for activities that have a close nexus to the underlying litigation. While a better course is to place all recovered money in the general fund, states may consider this option along with a bar on allocation of funds to outside organizations.²⁷⁶
- Require the AG to provide a quarterly or annual report to the legislature that includes, for each settlement or judgment, the aggregate recovery, the value of restitution to a state agency or consumers, amounts recovered for civil penalties, amounts recovered for attorneys’ fees, the AG’s use or planned use of the amounts received, and the balance of the AG’s fund. Arizona and Arkansas have such requirements.²⁷⁷

Future Targets

While many examples of problematic AG enforcement of UDAP laws explored in this report involve the pharmaceutical industry, a broad range of businesses are bracing themselves for similar actions.

The types of troubling enforcement practices discussed here apply to any industry. As this report shows, some of the most disconcerting litigation has targeted the marketing of prescription drugs. Pharmaceutical manufacturers have become prime targets because they are viewed as deep pockets by contingency fee lawyers who have partnered with state AGs. Given the success of this model in leading to lucrative settlements, these types of enforcement practices are likely to expand to new industries and types of conduct—some of these practices have arisen in cases involving nursing homes, mortgage lenders, and automobile manufacturers, among others.

Two areas where expanded AG use of UDAP enforcement actions appears particularly likely, with significant potential for misuse of these laws, are data breaches and food marketing practices.

Data Breaches

After a data breach, companies are often accused of having failed to adequately protect their customers' information. Historically, the FTC has taken the lead in privacy law enforcement. Now, with increased storage of consumer data and a rise in security breaches, state AGs and class action lawyers are increasingly bringing actions under state UDAP laws and other legal theories.

Many states have adopted statutes that specifically empower AGs to use their UDAP authority to enforce data security breach notification requirements.²⁷⁸ AGs have used these laws to impose penalties on companies when a data breach occurs, whether it results from an individual employee's carelessness or a malicious hacker.

“AGs have used these laws to impose penalties on companies when a data breach occurs, whether it results from an individual employee's carelessness or a malicious hacker.”

For example, Health Net settled claims with Connecticut AG Richard Blumenthal in 2010 and Vermont AG William Sorrell in 2011 after the insurer lost a hard drive that included protected health information. In addition to spending millions of dollars to provide private identity theft protection to individuals whose information was included on the hard drive, Health Net paid Connecticut \$250,000²⁷⁹ and Vermont \$55,000²⁸⁰ to settle these claims. There was no indication that anyone had actually accessed the information. The Connecticut settlement was hailed by Blumenthal as the “first of its kind in the nation.”²⁸¹

Massachusetts AG Martha Coakley entered a similar settlement in 2011 with a company that owns several popular bars and restaurants in the Boston area. In that instance, malicious code installed on The Briar Group’s computer systems allowed hackers to access customers’ credit card and debit card information.²⁸² The complaint alleged the business violated the state’s UDAP law by failing to adequately protect its customers’ personal information. Under the terms of the settlement, the company must adopt additional security measures and investigate any potential misuse of the stolen data and alert customers if there is evidence of fraudulent transactions. The company also agreed to pay the state \$110,000 in civil penalties.

Thus far, AG actions have been measured responses to data breaches compared to consumer class actions, which have sought substantial damages even in absence of evidence of misuse. But these class actions have faced significant legal challenges.²⁸³ It seems only a matter of time before a politically-connected private lawyer succeeds in convincing an AG to hire his or her firm to investigate and pursue potential data breaches on the state’s behalf. Such an alliance would allow private lawyers to leapfrog over their biggest hurdle in class actions—to show class members suffered an actual injury as required for standing. The aggregation of civil penalties based on each person whose data was potentially exposed, even if there is no evidence that it was actually misused, could result in extraordinary liability (and lucrative fees for private lawyers hired by the state).

“ *It seems only a matter of time before a politically-connected private lawyer succeeds in convincing an AG to hire his or her firm to investigate and pursue potential data breaches on the state’s behalf.* ”

Food and Beverage Marketing

Private lawyers have already circulated a pitch to state AGs suggesting that states hire them to bring lawsuits against food manufacturers and restaurant chains to hold them financially responsible for medical costs associated with obesity-related conditions.²⁸⁴ That letter suggested that AGs delegate the state's subpoena power under UDAP laws to private lawyers. They would use the state's power to attempt to find internal documents that could tarnish the public's perception of food makers²⁸⁵ and place targeted "big food defendants" at a distinct disadvantage even before filing suit.²⁸⁶ An investigation by *Politico* revealed that the law firm behind the proposal had circulated it to AGs in at least sixteen states.²⁸⁷

To date, no AG has taken the bait on that proposal, possibly as a result of public disclosure of the lawyers' marketing effort. In recent years, however, plaintiffs' attorneys, relying on UDAP laws, have filed a surge of consumer class actions challenging food marketing practices.²⁸⁸ The most popular style of these claims alleges that a product is misleadingly advertised as "natural" due to its processing or the presence of genetically-modified or other ingredients.

As their pitch to AGs to bring obesity-related litigation shows, plaintiffs' lawyers certainly are aware that bringing UDAP actions through state AGs, rather than as private class actions, can avoid challenges they face in such suits, such as showing consumers were actually injured by allegedly deceptive marketing and what, if any, loss consumers experienced. Instead, a state AG enforcement action would allow for significant civil penalties for each product sold.

“ In recent years, however, plaintiffs' attorneys, relying on UDAP laws, have filed a surge of consumer class actions challenging food marketing practices. The most popular style of these claims alleges that a product is misleadingly advertised as 'natural' due to its processing or the presence of genetically-modified or other ingredients. ”

AGs already bring UDAP actions against food makers. As discussed earlier, 39 AGs joined the FTC in a settlement with Dannon of claims alleging that the company exaggerated the health benefits of its Activia yogurt and its DanActive dairy drink.²⁸⁹ Time will tell whether AGs are willing to move from cases against food companies involving claimed nutritional benefits or health risks to partnering with private lawyers to bring the types of spurious claims that are more common in class action litigation.

Recommendations for Reform

State legal reform can address the unfair enforcement practices documented in this report while fully preserving the ability of state AGs to protect consumers from deceptive practices.

Each section of this report offers commonsense options for legal reform that would curtail the unfair enforcement of UDAP laws. These proposals were developed based on existing state statutes and court decisions. This section brings together and summarizes the reform options examined in greater depth in each section.

These reforms preserve a state AG's ability to quickly stop deceptive practices, obtain restitution for any consumer who suffered a loss, and impose civil penalties on those who willfully violate the law.

These reforms target areas where UDAP enforcement has strayed from these purposes. They address the specific types of problematic practices documented in this report by reducing incentives to bring enforcement actions for profit or politics, creating more consistency between UDAP actions and a business's compliance with government regulations, and curtailing the potential for excessive civil penalties.

While state UDAP laws share many characteristics, each statute is distinct. The reforms presented in this report are intended to generate ideas for state-specific changes to UDAP laws.

1. ADDRESS CONCERNS THAT ARISE WHEN STATE AGS DELEGATE UDAP ENFORCEMENT POWER TO CONTINGENCY FEE LAWYERS BY:

- Requiring the government to make a written finding that hiring outside counsel is cost-effective and in the public interest before taking such action;
- Subjecting the hiring process to competitive public bidding;
- Posting contingency fee contracts and payments made to private lawyers on a public website;
- Requiring outside counsel to maintain detailed time and expense records;
- Mandating that government lawyers maintain control over the litigation;

- Placing with the state exclusive authority to settle a case;
- Placing a sliding scale on contingency fees based on the amount recovered, along with a maximum fee cap; and
- Precluding lawyers from collecting fees based on a percentage of the civil penalties imposed; or
- Prohibiting state-hiring of outside counsel on a contingency fee basis unless specifically authorized by statute.

2. PROVIDE CONSISTENCY IN UDAP LAWSUITS AND REGULATION BY GOVERNMENT AGENCIES BY:

- Amending the state UDAP law to provide that the Act does not apply to “acts or practices permitted under laws of this State or the United States or under rules, regulations, or decisions interpreting such laws;”
- In states that already have such provisions, but where courts have interpreted them in a manner inconsistent with their purpose, amending the law as needed to preclude UDAP liability when the conduct at issue was permitted by government regulators; and

- Urging courts to find that informal letters issued by government agencies are more prejudicial than probative and are inadmissible as evidence under existing rules.

3. PROVIDE GREATER FAIRNESS AND PREDICTABILITY IN CIVIL PENALTIES, AND PROTECT DUE PROCESS RIGHTS BY:

- Authorizing civil penalties in instances in which a court finds that a business willfully engaged in an unfair or deceptive practice;
- Placing an aggregate limit on “per violation” civil penalties for “any related series of violations,” or alternatively, providing a cap linked to the actual harm to consumers or profit received by the business as a result of the violation;
- Providing that unfair or deceptive conduct that could harm consumers, but has not caused actual harm, is subject to an injunction to stop the practice and a lower civil penalty; and
- Providing courts with factors to guide them in determining a fair and reasonable civil penalty.

4. ENSURE UDAP SETTLEMENT MONEY IS PROPERLY USED TO PROTECT CONSUMERS AND REIMBURSE TAXPAYERS, NOT FOR POLITICAL SELF-PROMOTION, BY:

- Requiring all funds received, aside from money used for restitution of consumers or state agencies, to be deposited in the state's general fund and allocated through the ordinary legislative appropriation process;
- Allowing the AG to retain a portion of UDAP settlements and judgments exclusively to support of the office's consumer education and enforcement activities, and subjecting any AG fund to a maximum balance after which any additional funds go to the state's general fund;
- Prohibiting allocation of the state's recovery to outside organizations;
- Allowing the AG to distribute funds to a state agency only for activities that have a close nexus to the underlying litigation; or
- Requiring the AG to provide a quarterly or annual report to the legislature detailing the collection and use of money received from settlements and judgments.

Endnotes

- 1 See 51 Cong. Rec. 11,084–109, 11,112-16 (1914).
- 2 S. Rep. No. 74-2, at 1 (1936).
- 3 See 15 U.S.C. § 57b.
- 4 See 15 U.S.C. § 45(l).
- 5 See Executive Order 13433, Protecting American Taxpayers from Payment of Contingency Fees, 72 Fed. Reg. 28,441 (May 16, 2007).
- 6 Another significant difference between the FTC Act and state UDAP laws is that only the latter provides a private right of action. Private lawsuits under state UDAP laws have also raised significant concern for abuse. See, e.g., Henry N. Butler & Joshua D. Wright, Are State Consumer Protection Acts Really Little-FTC Acts?, 63 Fla. L. Rev. 163 (2011); Victor E. Schwartz & Cary Silverman, Common-Sense Construction of Consumer Protection Acts, 54 U. Kan. L. Rev. 1 (2005). Private lawsuits brought under UDAP laws are beyond the scope of this report.
- 7 See Lawsuit Ecosystem II: New Trends, Targets and Players 95-109 (Inst. for Legal Reform 2014); Unprincipled Prosecution: Abuse of Power and Profiteering in the New ‘Litigation Swarm’ (Inst. for Legal Reform 2014); Privatizing Public Enforcement (Inst. for Legal Reform 2013).
- 8 See Testimony of the Hon. Bill McCollum on Contingency Fees and Conflicts of Interest in State AG Enforcement of Federal Law, Statement Before the House Committee on the Judiciary Subcommittee on the Constitution (Feb. 2, 2012); James R. Copeland, Abuses in State AG Contingent-Fee Litigation and Dangers for Federal Delegation of Enforcement Authority, Statement Before the House Committee on the Judiciary Subcommittee on the Constitution (Feb. 2, 2012).
- 9 See, e.g., Manhattan Inst., Center for Legal Pol’y, Trial Lawyers, Inc., Attorneys General: A Report on the Alliance Between State AGs and the Plaintiffs’ Bar (2011).
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- 12 Exec. Order No. 13433, 72 Fed. Reg. 28,441 (May 16, 2007).
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- 18 *See id.*
- 19 Cohen Milstein has an entire section devoted to generating state AG actions. *See* Cohen Milstein, Practice Areas: Public Client (last visited Oct. 6, 2015). The firm, which is known for bringing class action lawsuits, has donated over \$70,000 to state AG campaigns over the past five years. *See* Jessica M. Karmasek, Cohen Milstein Law Firm Strengthening Relationships with State AGs, Earning Millions, Legal Newsline, Apr. 21, 2015.
- 20 Craig R. McCoy & Andela Couloumbis, As Penna. Targets Nursing Homes, Law Firm Could Benefit, Philadelphia Inquirer, June 1, 2015; *see also* Andrew Staub, Pennsylvania AG's Use of Outside Firms Draws Scrutiny, Pa. Independent, Sept. 2, 2015.
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- 22 *See id.*
- 23 *See id.*
- 24 *Id.* The amendment also increased Cohen Milstein's share from 10% to 14% of any recovery between \$100 million and \$200 million, and from 5% to 9% of any recovery over \$200 million. *See* Petitioners' Brief in Opposition to Respondents' Preliminary Objections to the *GGNSC Clarion LP v. Kane*, No. 165 MD 2015, Amended Petition for Review, at 4-5 (Pa. Commw., filed Sept. 28, 2015) (Petitioners' Brief).
- 25 McCoy & Couloumbis, *supra*.
- 26 Petitioners' Brief, *supra*, at 5.
- 27 *Id.* at 6.
- 28 McCoy & Couloumbis, *supra*.
- 29 *See id.*
- 30 *See generally* Petitioners' Brief, *supra*.
- 31 *See* Slip Op., *GGNSC Clarion LP v. Kane*, No. 165 M.D. 2015, at 22 (Pa. Commw. Jan. 11, 2016).
- 32 *Merck Sharp & Dohme Corp. v. Conway*, 947 F. Supp.2d 733 (E.D. Ky. 2013); *see also* Alison Frankel, Judge: Kentucky AG Can Use Contingency-fee Lawyers in Case vs Merck, Reuters, May 28, 2013.
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- 34 *Id.* at 746-47.
- 35 *Id.* at 750.
- 36 *Id.* at 745-50.
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- 46 Ken Ritter, Nev. AG, Fla. Firm Trade Barbs on 'Robo-Signing, Bloomberg Business, Dec. 16, 2011.

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- 53 *Lender Processing Servs. Inc. v. The Eighth Jud. Dist. Ct.*, No. 61387 (Nev.), appeal dismissed by stipulation Mar. 4, 2014.
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- 55 Transcript, Hearing on Motion to Compel, *Nevada v. Lender Processing Servs. Inc.*, No. A-11-653289-B (8th Jud. Dist. Ct., Clark County, Nev.), at 29 (Nov. 19, 2013).
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- 58 See Alex Berenson, 33 States to Get \$62 Million in Zyprexa Settlement, N.Y. Times, Oct. 6, 2008.
- 59 See John O’Brien, Judge Sides with Eli Lilly in Zyprexa Case, Legal Newsline, Dec. 1, 2009; John O’Brien, Zyprexa Settlements Piling Up, Four States Remain, W. Va. Rec., Sept. 21, 2009.
- 60 See *In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp.2d at 463-64.
- 61 See John O’Brien, Lilly Decides to Settle with AG Hood, Legal Newsline, Feb. 4, 2010.
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- 63 Chuck Bartels, Ark. Announces \$18.5 Million Settlement with Eli Lilly, Bloomberg Bus., Feb. 16, 2010.
- 64 *Marshall v. Jerrico, Inc.*, 446 U.S. 238, 249-50 (1980) (rejecting constitutional challenge but nonetheless recognizing requirement of neutrality and impartiality in enforcement proceeding); see also *Tumey v. Ohio*, 273 U.S. 510, 532 (1927).
- 65 *Young v. United States ex rel. Vuitton et Fils S.A.*, 481 U.S. 787, 804 (1987) (precluding lawyers prosecuting a criminal contempt action against individuals who violated an injunction against trademark infringement from having a financial stake in the case).
- 66 See *County of Santa Clara v. Super. Ct.* (Atlantic Richfield), 235 P.3d 21 (Cal. 2010); *State v. Lead Indus. Ass’n*, 951A.2d 428 (R.I. 2008).
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- 68 See *Merck*, 947 F. Supp. 2d at 733; Order Granting Defendant’s Motion for Summary Judgment, *Cephalon Inc. v. Wilson*, No. 2012-cp-40-07317 (S.C. Ct. of Com. Pleas, Richland County, June 6, 2014); *State ex rel. Discover Fin. Servs., Inc. v. Nibert*, 744 S.E.2d 625 (W. Va. 2013); Maria Chutchian, SC AG Can’t Skirt AstraZeneca Improper Penalty Claims, Law360, Dec. 21, 2011.
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- 71 See La. Act No. 796 (2015) (H.B. 799).
- 72 See Nev. Rev. Stat. § 228.110(1)(b) (as amended in 2015).
- 73 See *State v. Actavis Pharma, Inc.*, 2016 WL 1463904, No. 217-2016-CV-00566, at *8 (N.H. Super. Ct. Mar. 8, 2016) (interpreting N.H. Rev. Stat. Ann. §§ 7:6-f; 7:12).
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- 76 OPDP issues enforcement letters asking companies to stop marketing claims that its staff views as unsupported or misleading. These take the form of notice of violation letters (or “untitled letters”) for minor issues and warning letters for more serious concerns. OPDP issued nine enforcement letters in 2015 through August (seven untitled letters and two warning letters), an amount that is less than typical. See FDA, OPDP, Warning Letters 2015 (last visited Sept. 1, 2015). OPDP typically issues 30 to 50 enforcement letters each year).
- 77 FDA, Regulatory Procedures Manual § 4-1-1 (July 2012).
- 78 Brief for the Respondents, *Holistic Candles and Consumers Ass’n v. FDA*, No. 11-1454, 2012 WL 3991471, at *9-10 (U.S. Sept. 11, 2012); see also *Cody Labs., Inc. v. Sebelius*, 2010 WL 3119279, at *12 (D. Wyo. July 26, 2010) *aff’d in pertinent part*, 446 F. Appx. 964 (10th Cir. 2011) (“[R]egardless of any warning letters that the FDA may have sent to Defendants, it is clear that the FDA has not completed this investigation.”).
- 79 Memorandum in Support of Defendants’ Motion to Dismiss, *Cody Labs. v. Sebelius*, No. 10-CV-000147-ABJ, 2010, at 2 (D. Wyo. Aug. 30, 2010).
- 80 21 C.F.R. § 10.85(k).

- 81 *Holistic Candlers and Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 944 (D.C. Cir. 2012) (regarding warning letters finding that “[i]t is plain, therefore, that no legal consequences flow from the agency’s conduct to date, for there has been no order compelling the appellants to do anything.”) (Internal citations omitted); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (noting that letters do not “constitute a final decision by the FDA”); *Estee Lauder, Inc. v Food & Drug Admin.*, 727 F. Supp. 1, 6-7 (D.D.C. 1989) (FDA letter was not agency’s “final position”).
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- 91 *Id.* at 687.
- 92 *See id.* at 689-91.
- 93 *Id.* at 691.
- 94 *Id.*
- 95 *See* Litigation Retention Agreement for Special Counsel Appointed by the South Carolina Attorney General, July 19, 2016; *see also* John O’Brien, S.C. AG McMaster Taking Contributions From Outside Counsel He Hired, Legal Newswire, Sept. 24, 2009. McMaster, who later ran unsuccessfully for governor, gave back \$32,500 in donations from five lawyers he hired to work on these lawsuits. *See* John O’Brien, South Carolina’s Risperdal Suit Goes to Trial, Legal Newswire, Mar. 8, 2011.
- 96 Opening Statement, *State ex. rel. Wilson v. Janssen Pharma., Inc.*, No. 2007CP4201438, 2011 WL 2066648 at *12 (S.C. Com. Pl. Mar. 8, 2011).
- 97 Closing Statement, *State ex. rel. Wilson v. Janssen Pharma., Inc.*, No. 2007CP4201438, 2011 WL 2161889, at *8-9 (S.C. Com. Pl. Mar. 21, 2011).
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- 99 Penalty Order, *State ex. rel. Wilson v. Ortho-McNeil-Janssen Pharma., Inc.*, No. 2007CP4201438, 2011 WL 2185861 (S.C. Com. Pl. June 3, 2011).
- 100 *State ex. rel. Wilson v. Ortho-McNeil-Janssen Pharma., Inc.*, 777 S.E.2d 176, 204 (S.C. 2015), *cert. denied*, 2016 WL 100867 (Jan. 11, 2015).
- 101 *See, e.g., Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 940-43 (7th Cir. 2001) (finding Illinois Consumer Fraud and Deceptive Business Practices Act does not subject pharmaceutical makers to liability for statements authorized by federal law); *Prohias v. Pfizer, Inc.*, 490 F. Supp.2d 1228, 1234-35 (S.D. Fla. 2007) (interpreting safe harbors of the Florida and Massachusetts consumer fraud laws); *Duronio v. Merck & Co., Inc.*, No. 267003, 2006 WL 1628516, at *7 (N.D. Tex. June 13, 2006) (finding trial court properly dismissed claim under Michigan Consumer Protection Act because the pharmaceutical marketing activities underlying the claim are authorized and regulated under laws administered by the FDA); *White v. Wyeth*, 705 S.E.2d 828, 838 (W. Va. 2010) (finding, with respect to private rights of action, that the West Virginia Consumer Credit and Protection Act is not intended to cover prescription drug purchases because of the role of the physician in the consumer’s

- purchasing decision and the high degree of federal regulation of prescriptive drug product) (citing *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, (N.J. Super. App. Div. 2003), *cert. denied*, 837 A.2d 1092 (N.J. 2003) and *De Bouse v. Bayer AG*, 922 N.E.2d 309, 318 (Ill. 2009); *DePriest v. AstraZeneca Pharm., L.P.*, 351, S.W.2d 168, 178 (Ark. 2009) (finding that statements made in advertising that are supported by the FDA approved labeling fall within the safe harbor provision of the Arkansas Deceptive Trade Practices Act as being actions permitted under the laws administered by the FDA and are not actionable); *Prohias v. AstraZeneca Pharm., L.P.*, 958 So.2d 1054, 1056 (Fla. Dist Ct. App. 2007).
- 102 See Or. Dep't of Justice, Press Release, Oregon Office of the Attorney General, Attorney General Hardy Myers Files Judgment Against Merck and Company Resolving a Three-Year Investigation of the Company's Marketing of Vioxx, May 20, 2008.
- 103 See Stipulated Consent Judgment at 5, *Iowa ex Rel. Miller v. Merck & Co., Inc.* (Merck Stip. Judgment).
- 104 See *id.* at 6.
- 105 In the state AG settlement with Pfizer regarding its marketing of Celebrex and Bextra, the agreement included a provision that, in the event the FDA does not respond in 45 days, Pfizer may run the advertisement after contacting the Multistate Executive Committee of AGs and informing them they have not received feedback from the FDA on the promotional items. See Stipulated Consent Judgment at 6, *Oregon ex Rel. Meyers v. Pfizer Inc.* (Pfizer Stip. Judgment).
- 106 See 21 U.S.C. § 352(n). The agreement also imposed additional disclosure requirements for Continuing Medical Education presenters who have had a "promotional relationship" with Merck, and it imposed additional restraints on individuals who could serve on external Drug Safety Monitoring Boards that review Merck safety studies. The requirements went beyond the usual financial conflicts and included items on potential vague potential biasing conflicts such as "intellectual conflict" or "career involvement" with the product under study. Finally, the agreement imposed additional requirements for an individual to be identified as an author in a manuscript for a Merck-sponsored clinical trial. In order to prevent the "ghostwriting" or journal articles, the agreement provided that the author of an article must have made "substantial contribution to the conception and design, or acquisition of data, or analysis and interpretation of data." Merck Stip. Judgment at 6-10.
- 107 See Or. Dep't of Justice, Press Release, Attorney General Hardy Myers Files Judgment Against Pfizer, Inc. Resolving a Five-Year Investigation Into the Company's Marketing of Bextra and Celebrex, Oct. 22, 2008 (Oregon AG Pfizer Press Release). The agreement also included disclosure requirements for CME speakers, and it prevented the "ghostwriting" of articles and studies, using "mentorships" to pay physicians for time spent with Pfizer sales reps, using grants to encourage use of Pfizer products, using sales personnel to make grant decision that are supposed to be unrelated to marketing, and using patient testimonials to misrepresent a drug's efficacy.
- 108 See Pfizer Stip. Judgment, *supra*, at 11, 13.
- 109 See *id.* at 13.
- 110 See *id.* at 12; see also Oregon AG Pfizer Press Release, *supra*.
- 111 See *id.* at 11-12; The agreement did provide Pfizer a mechanism to modify the off-label requirements regarding the use of reprints if the FDA were to issue final guidance documents that materially conflicted with the agreement. See *id.* at 12-13.

- 112 Iowa Office of the Attorney General, Press Release, Miller, State Attorneys General Reach \$100 Million Settlement over Off-Label Marketing of Prescription Drug Depakote, May 7, 2012.
- 113 See Stipulated Consent Judgment at 8, *Iowa ex Rel. Miller v. Abbott Labs.* (Abbott Stip. Judgment).
- 114 See *id.* at 9-11.
- 115 See *id.* at 11.
- 116 See *id.* at 9-11.
- 117 See *id.* at 11-12.
- 118 See *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012).
- 119 See *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119F. Supp.3d 196, 226 (S.D.N.Y., 2015).
- 120 See *id.* at 225.
- 121 See *id.* at 224.
- 122 See David McAfee, Calif. Counties Claim Pharma Cos. Lied About Opioid Safety, Law360, May 22, 2014.
- 123 See Complaint for Violations of California False Advertising Law, California Unfair Competition Law, and Public Nuisance, Seeking Restitution, Civil Penalties, Abatement, and Injunctive Relief, *People of the State of California v. Purdue Pharma LP et al.*, Case No. 30-2014-00725287, at 97-99 (Orange Cnty. Sup. Ct., May 21, 2014).
- 124 See *id.*
- 125 See *id.* at 5.
- 126 See *id.* at 13-14, 33, 68, 70.
- 127 Lance Duroi, Chicago Sues Pharma Cos. Over Painkiller Marketing, Law360, June 3, 2014.
- 128 Y. Peter Kang, Drug Cos. Win Stay Of False Ad Suit Over Painkiller Safety, Law360, Aug. 28, 2015.
- 129 See Order Granting Motion to Stay, *Cal. v. Purdue Pharma LP.*, No. 2014-00725287 (Cal. Super. Ct. 2015).
- 130 See *id.*
- 131 See Memorandum Opinion and Order, *City of Chicago v. Purdue Pharma L.P.*, No. 14 C 4361 (N.D. Ill. Dec. 15, 2014).
- 132 See Memorandum Opinion and Order, *City of Chicago v. Purdue Pharma L.P.*, No. 14 C 4361 (N.D. Ill. May 8, 2015).
- 133 See Sindhu Sundar, Chicago Improves Opioid Case With Details About Doctors, Law360, Nov. 24, 2015.
- 134 See Kat Greene, Nursing Home Operators Blast Pa. AG's Hire of Cohen Milstein, Law360, Oct. 1, 2015.
- 135 See *id.* at 6.
- 136 Complaint and Petition for Injunctive Relief, *Commonwealth of Pa. v. Golden Gate Nat'l Senior Care LLC*, No. 336 MD 2015 (Commonwealth Ct. of Pa., filed June 30, 2015).
- 137 Petitioners' Brief, in Opposition to Respondents' Preliminary Objections to the *GGNSC Clarion LP v. Kane*, No. 165 MD 2015, Amended Petition for Review, at 5 (Pa. Commw., filed Sept. 28, 2015).
- 138 Complaint and Petition for Injunctive Relief, *supra*, at 91.
- 139 *Id.* (citing 28 PA. Code Ch. 201 and 211).
- 140 See 35 Pa. Stat. § 448.813(a); 28 Pa. Code §§ 201.2 and 211.12(l); 42 U.S.C. §§ 1395aa, 1395i-3(g), 1396r(g).
- 141 35 Pa. Stat. § 448.817(a).

- 142 See 42 U.S.C. §§ 1395aa, 1395i-3g, 1396a, 1396r, and 55 Pa. Code § 1187.21.
- 143 *Id.*
- 144 Petitioners' Brief, *GGNSC Clarion LP v. Kane*, *supra*, at 10.
- 145 *Id.* at 16.
- 146 See *id.* at 16-17 (citing 28 Pa. Code § 211.12(i)).
- 147 See Slip Op., *GGNSC Clarion LP v. Kane*, No. 165 M.D. 2015, at 15-16 (Pa. Commw. Jan. 11, 2016).
- 148 See, e.g., D.C. Code Ann. § 28-3904 (stating that a person violates the law "whether or not any consumer is in fact misled, deceived or damaged thereby"); Md. Code Ann., Com. Law §§ 13-301(1), 13-302 (providing that the capacity or tendency to deceive establishes a violation "whether or not any consumer in fact has been misled, deceived, or damaged as a result of that practice"); *People ex rel. Lockyer v. Fremont Life Ins. Co.*, 104 Cal. App. 4th 508 (Cal. Ct. App. 2002) (finding the test is whether the public is likely to be deceived even if no one was actually deceived, relied upon the fraudulent practice or sustained an damages); *State ex rel. McLeod v. Brown*, 294 S.E.2d 781, 783 (S.C. 1982) (finding a tendency to deceive and mislead without proof of actual deception is sufficient to establish liability).
- 149 See, e.g., Ala. Code § 8-9-11(b); Ariz. Rev. Stat. § 44-1531(A); Del. Code tit. 6, §§ 2522(b), 2533(e); Fla. Stat. Ann. § 501.2075; Ind. Code Ann. § 24-5-0.5-4(g); Mass. Gen. Laws ch. 93A, § 4; Miss. Code Ann. § 75-24-19(1)(b); Mont. Code Ann. § 30-14-111(2); Nev. Rev. Stat. § 598.0999(2); N.M. Stat. Ann. § 57-12-11; Or. Rev. Stat. § 646.642(3); 73 Pa. Stat § 201-8(b); S.C. Code Ann. § 39-5-110(a); Va. Code Ann. § 59.1-206(A); Wyo. Stat. § 40-12-113(c); see also La. Rev. Stat. § 51:1407(B) (requiring "intent to defraud"); Me. Rev. Stat. Ann. tit. 5 § 209 ("intentional"); Mich. Comp. Laws § 445.905(1) ("persistent and knowing"); S.D. Cod. Laws § 37-24-27 ("intentional").
- 150 Some courts have required higher burden of proof to establish liability for civil penalties. See, e.g., *Chatham Racquet Club v. Commonwealth of Pa.*, 561 A.2d 354 (Pa. Commw. Ct. 1989) (finding statutory language requires the Commonwealth to show that the conduct was in fact fraudulent); *Stevenson v. Louis Dreyfus Corp.*, 811 P.2d 1308, 1311 (N.M. 1991).
- 151 The Illinois Consumer Fraud Act authorizes a civil penalty not to exceed \$50,000, or \$50,000 *per violation* when court finds an *intent to defraud*. See 815 Ill. Comp. Stat. 505/7(b). Several states authorize a \$1,000 civil penalty per violation, which may still rise to substantial sums when aggregated. D.C. Code Ann. § 28-3905(i); Md. Code Ann., Com. Law § 13-410; Mo. Rev. Stat. § 407.100(6); 73 Pa. Stat § 201-8(b); Tenn. Code Ann. § 47-18-108(b)(3); Va. Code Ann. § 59.1-206(C).
- 152 See, e.g., Ariz. Rev. Stat. § 44-1531.A; Ark Code Ann. § 4-88-113; Del. Code Ann. tit. 6 § 2522(b); Fla. Stat. Ann. § 501.2075; Haw. Rev. Stat. Ann. § 480-15.1; 815 Ill. Comp. Stat. 505/7(b); Kan. Stat. Ann. § 50-636; Me. Rev. Stat. Ann. tit. 5 § 209; Miss. Code Ann. § 75-24-19(1)(b); Mont. Code Ann. § 30-14-142(2); N.H. Rev. Stat. Ann. § 358-A:4(III)(b); N.J. Stat. Ann. § 56:8-13; Okla. Stat. Ann. tit. 15, § 761.1(C); Vt. Stat. Ann. tit. 9, § 2458(b) (1); Wis. Stat. Ann. § 100.26; Wyo. Stat. Ann. § 40-12-113.
- 153 See, e.g., Alaska Stat. § 45.50.551(b) (\$25,000); Iowa Code § 714.16(7) (\$40,000); Mich. Comp. Laws § 445.905 (\$25,000); Minn. Stat. § 8.31(3) (\$25,000); Ohio Rev. Code § 1345.07(D) (\$25,000); Or. Rev. Stat. § 646.642 (\$25,000); Tex. Bus. & Com. Code § 17.47(c) (\$20,000).

- 154 See, e.g., Cal. Bus. & Prof. Code § 17206.1 (additional \$2,500 civil penalty for acts against elderly or disabled); Colo. Rev. Stat. § 6-1-112 (penalty increased from \$2,000 to \$10,000 for violations against the elderly); Fla. Stat. § 501.2077 (penalty increased from \$10,000 to \$15,000 for violations against the elderly); 815 Ill. Comp. Stat. 505/7(c) (additional \$10,000 penalty for violation against the elderly); Iowa Code § 714.16(A) (additional \$5,000 penalty for violation against the elderly).
- 155 See, e.g., N.J. Stat. Ann. § 56:8-14 (penalty increased from \$10,000 for first violation to \$20,000 for subsequent violations); Md. Code Ann., Com. Law § 13-410 (\$1,000 per violation increased to \$5,000 per violation for subsequent violations).
- 156 See 15 U.S.C. § 57b.
- 157 See Stipulated Order for Permanent Injunction and Monetary Judgment, *FTC v. Sale Slash, LLC*, No. CV15-03107 PA (AJWx) (C.D. Cal. Feb. 1, 2016).
- 158 See 15 U.S.C. § 45(l); 16 C.F.R. § 1.98 (adjusting civil penalty from \$10,000 provided by FTC Act to \$16,000 per violation).
- 159 See FTC, A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority (July 2008).
- 160 15 U.S.C. § 45(m)(1)(B)).
- 161 A handful of states require the state AG to contact a business before filing a UDAP enforcement action, but permit the AG to seek civil penalties even if the business offers to immediately address the concern. See, e.g., Me. Rev. Stat. Ann. tit. 5, § 209 (requiring AG to provide a person with at least 10 days' notice of the intended action, and give the person an opportunity to confer with the AG); N.Y. Gen. Bus. Law § 349(c) (requiring AG to give business notice and an opportunity to show in writing within five business days why proceedings should not be instituted, unless AG finds notice is not in the public interest); Tenn. Code Ann. § 47-18-108 (requiring ten days' notice).
- 162 Rhode Island appears to be the only state that requires a violation of the terms of an injunction before imposing civil penalties. See R.I. Gen. Laws § 6-13.1-8.
- 163 See generally Constitutional Constraints: Provisions Limiting Excessive Government Fines (U.S. Chamber Inst. for Legal Reform 2015); see also Brief of the Chamber of Commerce of the United States as *Amicus Curiae* in Support of Petitioner, *Ortho-McNeil-Janssen Pharmaceutical, Inc. v. South Carolina*, No. 15-600 (filed Dec. 9, 2015) (urging court to grant certiorari to consider whether \$124 million civil penalty in UDAP action obtained by contingency fee lawyers representing state, without evidence of injury to public, violates Excessive Fines Clause).
- 164 See *State ex. rel. Wilson v. Ortho-McNeil-Janssen Pharma., Inc.*, 777 S.E.2d 176 (S.C. 2015).
- 165 S.C. Code Ann. § 39-5-100(a).
- 166 *Wilson*, 777 S.E.2d at 193.
- 167 See *id.* at 187.
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- 173 Brief of Amicus Curiae the South Carolina Chamber of Commerce, *State ex. rel. Wilson v. Ortho-McNeil-Janssen Pharma., Inc.*, No. 2012-206987, 2013 WL 8656704, at *4, *15 (S.C. filed Jan. 14, 2013).

- 174 *Wilson*, 777 S.E.2d at 206.
- 175 *See id.* at 204-05.
- 176 *Id.* at 204.
- 177 *Id.* at 203 n.31.
- 178 *See id.* at 203-04.
- 179 *See id.* at 204.
- 180 *See id.*
- 181 *See id.* at 197-200.
- 182 *See id.* at 205.
- 183 *See id.* at 206 n.33.
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- 185 Miss. Code Ann. § 75-24-19(1)(b).
- 186 *See In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp.2d 397, 458 (E.D.N.Y. 2009).
- 187 *See id.*
- 188 *See id.* at 458-59.
- 189 *Id.* at 459.
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- 198 DOJ Press Release. Pharmaceutical Company Eli Lilly to Pay Record \$1.415 Billion for Off-Label Drug Marketing, Jan 9, 2009.
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- 209 For example, the Consumer Product Safety Act, 15 U.S.C. § 2069(a)(1), includes a \$15 million cap on civil penalties for any related series of violations. Statutes administered by National Highway Traffic Safety Administration (NHTSA) also include aggregate civil penalty caps "for a related series of violations" or "for a related series of daily violations" ranging from \$1 million to \$35 million depending on the type of violation at issue. See 49 U.S.C. § 30165(a)(1), (a)(2) (B), (a)(3), (a)(4).
- 210 There is a long history of use of treble damages as an appropriate level of punishment in UDAP and other laws. See *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 507 (2008).
- 211 For example. NHTSA considers: (1) the nature of the defect or noncompliance; (2) knowledge by the person charged of its obligations under this chapter; (3) the severity

- of the risk of injury; (4) the occurrence or absence of injury; (5) the number of motor vehicles or items of motor vehicle equipment distributed with the defect or noncompliance; (6) actions taken by the person charged to identify, investigate, or mitigate the condition; (7) the appropriateness of such penalty in relation to the size of the business of the person charged, including the potential for undue adverse economic impacts; (8) whether the person has been assessed civil penalties under this section during the most recent five years; and (9) other appropriate factors. 49 U.S.C. § 30165(c). The Consumer Product Safety Administration (CPSC) considers: (1) the nature of the product defect; (2) the severity of the risk of injury; (3) the occurrence or absence of injury; (3) the number of defective products distributed; (4) the appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses; and (5) other factors as appropriate. 16 C.F.R. § 1119.4.
- 212 An example of a state UDAP law that includes penalty factors is the North Carolina Unfair and Deceptive Trade Practices Act. It provides that “[i]n determining the amount of the civil penalty, the court shall consider all relevant circumstances, including, but not limited to, the extent of the harm caused by the conduct constituting a violation, the nature and persistence of such conduct, the length of time over which the conduct occurred, the assets, liabilities, and net worth of the person, whether corporate or individual, and any corrective action taken by the defendant.” N.C. Code Ann. § 75-15.2. California’s Unfair Competition Law similarly provides that a court may consider: “the nature and seriousness of the misconduct, the number of violations, the persistence of the misconduct, the length of time over which the misconduct occurred, the willfulness of the defendant’s misconduct, and the defendant’s assets, liabilities, and net worth.” Cal. Bus. & Prof. Code § 17206(b). In Texas, the jury (not the court) decides whether to award a civil penalty and the amount. Tex. Bus. & Com. Code § 17.47(c). In awarding a civil penalty, Texas’s deceptive trade practices law instructs the trier of fact to consider: “(1) the seriousness of the violation, including the nature, circumstances, extent, and gravity of any prohibited act or practice; (2) the history of previous violations; (3) the amount necessary to deter future violations; (4) the economic effect on the person against whom the penalty is to be assessed; (5) knowledge of the illegality of the act or practice; and (6) any other matter that justice may require.” *Id.* §17.47(g).
- 213 *Wilson*, 777 S.E.2d at 203 n.31, *see also United States v. Reader’s Digest Ass’n, Inc.*, 662 F.2d 955, 967 (3d Cir. 1981) (in determining civil penalty under FTC Act, considering “(1) the good or bad faith of the defendants; (2) the injury to the public; (3) the defendant’s ability to pay; (4) the desire to eliminate the benefits derived by a violation; and (5) the necessity of vindicating the authority of the FTC”); *Com. v. Fall River Motor Sales, Inc.*, 565 N.E.2d 1205, 1211 (Mass. 1991) (applying same FTC factors to affirm \$20,000 civil penalty under Massachusetts consumer protection law); *State by Humphrey v. Alpine Air Products, Inc.*, 490 N.W.2d 888, 897 (Minn. Ct. App. 1992) (applying first four factors to affirm \$70,000 civil penalty under Minnesota consumer protection statutes).
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- 215 Sarah D. Wire, Officers’ Agenda in Books: Prison Overhaul, Tax Cut Now Law, Ark. Democrat Gazette, May 3, 2011.
- 216 Dan Greenberg, Why is Dustin McDaniel Superseding the Legislature and Breaking the Law, Advance Arkansas Institute, June 10, 2011.
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- 228 Tony Saavedra, Toyota Settles with O.C. D.A. for \$16 Million, Orange County Register, Aug. 21 2013.
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- 245 Jim Harger, Michigan Attorney General Mike Cox Says He's "Dumbfounded" that Grand Rapids, Kent County Leaders Are Questioning \$500,000 in Local Park Donations, Grand Rapids Press, Mar. 20, 2009.
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- 274 See N.H. Rev. Stat. § 7:6-f.
- 275 The statute provides: "[a]ny funds received by the attorney general on behalf of the state or its citizens as a result of any civil judgment or settlement of a claim, suit, petition, or other action under RSA 358-A or related consumer protection statutes shall be deposited in a consumer protection escrow account. The consumer protection escrow account shall at no time exceed \$5 million, with any amount in excess of \$5 million deposited into the general fund." *Id.*
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