



Washington Legal Foundation
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WLF Month in Review

This new WLF Litigation Division feature highlights WLF's court and agency filings, as well as decisions issued in response to WLF's filings. In this inaugural edition, we list June and July 2018 developments.

New Filings

- Plaintiffs in False Claims Act suits must demonstrate that the allegedly false claims were actually material to the government's payment decision.
- Patent holders' property rights should not be eviscerated based on a finding that their counsel in an infringement action engaged in litigation misconduct.
- In drafting regulations governing "bioengineered" labeling for food products, the Department of Agriculture must be mindful of the First Amendment rights of food producers.
- EPA should take cost-benefit considerations into account whenever it drafts new environmental regulations.
- FDA is imposing unwarranted regulatory requirements on medical-device manufacturers by improperly classifying some devices as "drugs."
- Suits alleging that companies engaged in an antitrust conspiracy should be dismissed early on, in the absence of factual allegations supporting the conspiracy claim.
- If workers chose to bring personal belongings to work in a bag, they are not entitled to be paid for the time it takes to inspect the bag.
- Property owners who allege that the government has taken their property without paying compensation ought to be permitted to assert those claims in federal court.
- Before California requires manufacturers to place Prop 65 cancer warnings on their products, they have a right to a hearing on whether the products cause cancer.
- After alien felons complete their prison sentences, they should remain in federal detention while awaiting deportation proceedings.

Cases Decided

- U.S. Supreme Court overturns appeals court decision that upheld Berkeley ordinance requiring health warnings on cell phones.
- U.S. Supreme Court prohibits SEC from conducting enforcement hearings before administrative law judges not properly appointed as "officers" of the United States.
- U.S. Supreme Court agrees to decide whether antitrust claims may be asserted by individuals who did not directly purchase from the alleged antitrust violator.
- U.S. Supreme Court declines to hear challenge to New York State law that abrogates contract and property rights of workers' compensation insurers.
- U.S. Supreme Court enforces a reasonable statute of limitations for the filing of class actions.
- Fourth Circuit affirms exclusion of "expert" testimony from a products-liability lawsuit where the experts deviated from accepted scientific standards in concluding the defendant's drug caused the plaintiffs' illnesses.

Litigation is the backbone of WLF's public-interest mission. We litigate nationally before state and federal courts and agencies. Our team, often with the *pro-bono* assistance of leading private attorneys, litigates original actions, files *amicus* briefs, participates in the regulatory process, and provides constitutional analysis before federal agencies and Congress.

If you become aware of a pending legal or regulatory matter in which WLF's unique public-interest participation would advance economic liberty, please contact WLF Chief Counsel Richard Samp.

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NEW FILINGS

Plaintiffs in False Claims Act suits must demonstrate that the allegedly false claims were actually material to the government's payment decision.

United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.

WLF urged the entire U.S. Court of Appeals for the Sixth Circuit to rehear a panel decision expanding liability under the False Claims Act. A relator suing under the FCA must show that any misrepresentation a defendant made to the government was material to the government's decision to pay the defendant's claims. The relator here accused a home-health agency of submitting Medicare reimbursement claims that failed to divulge the agency's violation of a rule governing when a doctor must sign a certification. The agency obtained the certifications; the relator alleged merely that it took too long to do so. WLF argues that the panel should have accounted for the fact that the government badly needs healthcare providers to participate in the Medicare program.

Patent holders' property rights should not be eviscerated based on a finding that their counsel in an infringement action engaged in litigation misconduct.

Regeneron Pharmaceuticals, Inc. v. Merus N.V.

WLF filed a brief in the U.S. Supreme Court, urging it to review (and overturn) an appeals court decision that substantially expands the "inequitable conduct" defense and thereby throws into question the continued viability of numerous patents. WLF's brief argued that the inequitable-conduct doctrine is being invoked far too frequently to strike down patents for relatively trivial errors. WLF asserted that patents should never be invalidated on inequitable-conduct grounds in the absence of "clear and convincing" evidence that the patentee withheld documents from its patent application with "intent to deceive" the Patent and Trademark Office. The alleged infringer presented no such evidence in this case.

In drafting regulations governing "bioengineered" labeling for food products, the Department of Agriculture must be mindful of the First Amendment rights of food producers.

In re USDA 'Bioengineered' Food Labeling

WLF filed formal comments with the U.S. Department of Agriculture, urging it not to require manufacturers of highly refined food products (such as oils and sugars) to bear "bioengineered" labeling—even if the products were made from bioengineered ingredients. WLF argued that including highly refined products within USDA's labeling mandate would contravene Congress's direction and would violate food manufacturers' First Amendment rights by requiring them to convey information that is neither factual nor uncontroversial.

EPA should take cost-benefit considerations into account whenever it drafts new environmental regulations.

In re Increasing Consistency and Transparency in Considering Costs and Benefits in Rulemaking

WLF filed formal comments with the Environmental Protection Agency (EPA), urging it to adopt an agency-wide standard requiring quantitative cost-benefit analyses of pollution standards. WLF's comments criticize EPA's former experimentation with "social" costs and benefits, which led to arbitrary and excessive regulation. Instead, EPA should take an objective approach to cost-benefit analysis and consider both the environment and the economy.

FDA is imposing unwarranted regulatory requirements on medical-device manufacturers by improperly classifying some devices as “drugs.”

In re FDA Product Jurisdiction Rule

WLF filed formal comments with the Food and Drug Administration (FDA), urging the agency to revise its proposed regulations governing how it classifies a medical product (*e.g.*, a drug, a medical device, or a biological product) for which a manufacturer seeks FDA marketing approval. WLF argued that the proposed regulations are inconsistent with FDA’s statutory mandate and improperly skew decision-making in favor of a drug classification. It can often be difficult to differentiate a “drug” from a “medical device”; federal law defines those two categories of medical products quite similarly. The principal distinction focuses on whether the product “achieve[s] its primary intended purposes through chemical action.”

Suits alleging that companies engaged in an antitrust conspiracy should be dismissed early on, in the absence of factual allegations supporting the conspiracy claim.

Quality Auto Painting Ctr. of Roselle, Inc. v. State Farm Indem. Co.

WLF asked the full U.S. Court of Appeals for the Eleventh Circuit to affirm the dismissal of several antitrust complaints against dozens of auto insurers. The case arises from the consolidated claims of several auto-body shops against 89 insurance companies, accusing the defendants of violating the Sherman Antitrust Act by conspiring to fix auto-repair reimbursement rates and to boycott certain body shops. WLF’s brief warned that the plaintiffs’ urged pleading standard, if adopted, would permit an antitrust complaint to allege merely parallel conduct among competitors as a sufficient basis for pleading an illegal agreement among competitor defendants.

If workers chose to bring personal belongings to work in a bag, they are not entitled to be paid for the time it takes to inspect the bag.

Frlekin v. Apple, Inc.

WLF asked the California Supreme Court to clarify that an employer need not pay an employee for the time she spends using an optional perk or service the employer provides its employees. The question at issue turns on the meaning of “hours worked” under California’s Wage Order No. 7, which requires an employer to pay each employee for all time the employee spends “subject to the employer’s control” or that the employer “suffers or permits” the employee to “work.” WLF’s *amicus* brief argued that because adopting the plaintiffs’ construction of the wage order would render it unconstitutionally vague, the court should avoid that interpretation.

Property owners who allege that the government has taken their property without paying compensation ought to be permitted to assert those claims in federal court.

Knick v. Township of Scott

WLF filed a brief in the U.S. Supreme Court, urging it to overrule a 1985 precedent that prevents individuals claiming a violation of their Fifth Amendment property rights from bringing their claims in federal court. WLF argued that the federal courts have traditionally been open to anyone asserting a violation of his constitutional rights and that there is no valid reason to deny that same privilege to property-rights claimants. WLF asserted that the 1985 precedent was based on a misreading of the Fifth Amendment.

Before California requires manufacturers to place Prop 65 cancer warnings on their products, they have a right to a hearing on whether the products cause cancer.

Monsanto Co. v. Office of Environmental Health Hazard Assessment

WLF filed a brief with the California Supreme Court asking it review and overturn an appeals court decision that rejected a challenge to the California Office of Environmental Health Hazard Assessment's (OEHHA) controversial listing of glyphosate as a potential carcinogen under its Prop 65 warning regime. WLF argued that OEHHA's reliance on the International Agency for Research on Cancer (IARC)—a private, politically unaccountable organization—to add glyphosate to the Prop 65 list constitutes an improper delegation of rulemaking authority in violation of the California Constitution's separation of powers.

After alien felons complete their prison sentences, they should remain in federal detention while awaiting deportation proceedings.

Nielsen v. Preap

WLF—acting for 10 Members of Congress—filed a brief in the U.S. Supreme Court, urging it to enforce a 1996 federal statute that requires the detention of aliens convicted of serious crimes while they contest the government's efforts to deport them. WLF argued that the mandatory-detention statute, 8 U.S.C. § 1226(c), applies even if immigration officials do not take custody of an alien immediately following his release from criminal incarceration. WLF's clients are U.S. Reps. Andy Biggs, Dave Brat, Scott DesJarlais, Paul Gosar, Andy Harris, Jody Hice, Walter Jones, Steve King, Doug LaMalfa, and Ted Yoho.

CASES DECIDED

U.S. Supreme Court overturns appeals court decision that upheld Berkeley ordinance requiring health warnings on cell phones.

CTIA—The Wireless Association v. City of Berkeley

The U.S. Supreme Court "GVR'd" a certiorari petition that challenged a Berkeley, California ordinance that requires all cell-phone retailers to post notices suggesting that normal cell-phone usage is dangerous. The Court granted the petition, vacated the lower-court decision upholding the ordinance, and remanded the case for reconsideration in light of an earlier High Court decision that significantly expanded commercial speech rights. The Court's action was a victory for WLF, which filed a brief urging the Court to grant the petition.

U.S. Supreme Court prohibits SEC from conducting enforcement hearings before administrative law judges not properly appointed as "officers" of the United States.

Lucia v. Securities and Exchange Commission

The U.S. Supreme Court vacated a final order of the U.S. Securities and Exchange Commission (SEC) that violated the Constitution by placing federal enforcement authority in the hands of an administrative law judge (ALJ) who was not properly appointed as an "Officer of the United States" under the Appointments Clause. The decision was a victory for WLF, which filed a brief in the case urging strict adherence to the Constitution's structural protections, including the Appointments Clause. The Court also held that because the ALJ decided Lucia's case without a constitutional appointment, he may not now rehear the case as though he had not decided it before. Instead, "[t]o cure the constitutional error, another ALJ (or the Commission itself) must hold a new hearing."

U.S. Supreme Court agrees to decide whether antitrust claims may be asserted by individuals who did not directly purchase from the alleged antitrust violator.*Apple, Inc. v. Pepper*

The U.S. Supreme Court agreed to review a U.S. Court of Appeals for the Ninth Circuit decision that exposes antitrust defendants to multiple recoveries. The decision was a victory for WLF, which filed a brief urging that review be granted. In order to prevent the possibility of multiple recoveries arising from a single course of conduct, the Supreme Court ruled 40 years ago that standing to assert claims for antitrust damages is limited to the immediate victims of the anticompetitive conduct—the direct purchasers. The Ninth Circuit adopted an extremely broad definition of who qualifies as a “direct purchaser,” an outcome that would complicate antitrust litigation and expose numerous companies to duplicative claims. WLF argued that the appeals court decision is inconsistent with Supreme Court precedent and threatens to chill the very sorts of competition that the antitrust laws are designed to encourage.

U.S. Supreme Court declines to hear challenge to New York State law that abrogates contract and property rights of workers’ compensation insurers.*American Economy Ins. Co. v. State of New York*

The Supreme Court declined to review a New York law that retroactively imposed a massive monetary obligation on insurance carriers to pay workers’ compensation benefits that they never agreed to pay under their insurance policies. The decision was a setback for WLF, which filed a brief urging review arguing that the statute violates several constitutional provisions designed to restrain government authority, including the Contracts and Takings Clauses.

U.S. Supreme Court enforces a reasonable statute of limitations for the filing of class actions.*China Agritech, Inc. v. Resh*

The U.S. Supreme Court issued a decision that enforces a reasonable limitations period in class actions. The decision was a victory for WLF, which filed a brief urging the Court to reject efforts by the plaintiffs’ bar to authorize the filing of long-delayed class actions simply because another lawsuit was pending in the years prior to the class-action filings. A two-year statute of limitations applies to securities fraud lawsuits. Under current law, the statute is tolled with respect to individual claims while a putative class action is pending; absent class members have an opportunity to file their own suit if the court hearing that case denies a motion for class certification. But if the two-year limitations period has expired, an absent class member should not be permitted to file a second class action on behalf of other shareholders, the court held. Otherwise, the plaintiffs’ bar could file class actions seriatim in hopes that one eventually would be certified.

Fourth Circuit affirms exclusion of “expert” testimony from a products-liability lawsuit where the experts deviated from accepted scientific standards in concluding the defendant’s drug caused the plaintiffs’ illnesses.*In re: Lipitor Marketing, Sales Practices and Products Liability Litigation*

The Fourth Circuit upheld an MDL court’s orders excluding as unreliable the plaintiffs’ expert testimony and granting summary judgment to Pfizer, the maker of Lipitor. The decision was a victory for WLF, which filed an *amicus* brief urging affirmance of the district court’s rigorous application of *Daubert’s* gatekeeping standard for ensuring the reliability of expert evidence. WLF argued that the district court acted well within its discretion in excluding the plaintiff’s expert opinions and that, without such expert testimony, the plaintiffs could not establish causation. The appeals court panel agreed that because the plaintiffs’ experts failed to demonstrate any association between Lipitor and diabetes, summary judgment for Pfizer was appropriate.