

Emerging Contaminants of Concern: Pharmaceuticals and Personal Care Products

In recent years, studies have confirmed the presence of pharmaceuticals and personal care products, such as cosmetics, in U.S. rivers, lakes, and streams. A 2002 study by the United States Geological Survey, which included sampling of 139 streams in 30 states, detected an average of seven chemical compounds including steroids, nonprescription drugs, and antibiotics, in the sampled streams. See *Pharmaceuticals, Hormones, and Other Contaminants in U.S. Streams*, <http://toxics.usgs.gov/pubs/FS-027-02/>. Similarly, a 2008 Associated Press survey found at least one pharmaceutical in the drinking water supplies of 24 major metropolitan areas. See *An AP Investigation: Pharmaceuticals Found in Drinking Water*, http://hosted.ap.org/specials/interactives/pharmawater_site/. These findings have led the United States Environmental Protection Agency (EPA) to classify pharmaceuticals and personal care products (PPCPs) as emerging contaminants of concern and have spurred investigations into the effect PPCPs may have on the environment and human health. Because many pharmaceutical compounds were only detected at very low levels, the effect, if any, on human health is unclear.

PPCPs enter the water supply through excretion by the body and the disposal of unused pharmaceuticals through sinks, drains, and toilets. Traditional wastewater treatment technology does not completely remove many pharmaceutical compounds. Disposal of pharmaceutical wastes is not currently regulated under the Resource Conservation and Recovery Act (RCRA) except to the extent that the products are deemed "hazardous wastes" meaning that they are specifically listed as a hazardous waste by EPA or exhibit one of the following characteristics: ignitability, corrosivity, reactivity, and toxicity. Because the chemicals in many pharmaceuticals do not meet the "hazardous waste" definition, disposal, including large-scale disposal by hospitals and long-term care facilities, has been largely unregulated by environmental laws.

In August 2010, EPA released a draft guidance document, "Best Management Practices for Unused Pharmaceuticals at Health Care Facilities," which describes techniques that health care facilities can implement to identify and properly manage unused pharmaceuticals. A copy of the draft report is available at <http://water.epa.gov/scitech/wastetech/guide/upload/unuseddraft.pdf>. Several states—including California, New Jersey, Connecticut, and New York—have implemented or are considering imposing requirements on the disposal of pharmaceuticals. As more information is developed regarding the effects of pharmaceutical and personal care product contamination, increased regulation of pharmaceuticals at all levels—federal, state, and local—can be expected.

ADDITIONAL ITEMS OF INTEREST:

Civil Enforcement

Honeywell to Pay Civil Penalty and Upgrade Pollution Controls at Plant

In March, Honeywell Resins and Chemicals LLC agreed to pay a \$3 million penalty for alleged Clean Air Act violations at its Hopewell, Virginia plant. The company will also upgrade the plant's air pollution controls. The facility, the world's largest single-site producer of caprolactam, an ingredient used in the manufacture of synthetic fibers, allegedly violated Clean Air Act limits on emissions of nitrogen oxide and benzene, in addition to other VOCs and particulate matter. Honeywell must also perform a mitigation project at the Virginia plant.

Weylchem US, Inc. to Resolve Violations of Pollution Laws at Facilities in South Carolina

In March, Weylchem agreed to pay a civil penalty of \$500,000 and perform corrective action measures to resolve the air, water, and solid waste pollution law violations at its specialty chemical manufacturing facility in Elgin and wastewater treatment plant in Lugoff, South Carolina. Weylchem has agreed to eliminate discharges to the Wateree River and cease the trucking of waste from Elgin to Lugoff. In addition, Weylchem will investigate both plants for additional potential environmental impacts and correct those issues.

Settlement Reached with Tyson Foods Regarding Releases

The U.S. Department of Justice and the EPA announced in early April a settlement with Tyson Foods to address releases of anhydrous ammonia at facilities in Kansas, Missouri, Iowa, and Nebraska. The releases followed incidents which resulted in multiple injuries, property damage, and one fatality. As a result of the settlement, Tyson will conduct third-party audits at all facilities in the affected states to ensure compliance with the Clean Air Act's Risk Management Program and test piping in its refrigeration systems. In addition, it will pay a \$3.95 million penalty and purchase emergency response equipment for first responders near its facilities.

Cemex, Inc. to Pay \$1 Million CAA Civil Penalty

In April, EPA and the U.S. Department of Justice announced a settlement with Cemex, Inc. to resolve Clean Air Act (CAA) violations at its Lyons, Colorado cement manufacturing facility. Cemex will pay a \$1 million civil penalty and install Selective Non-Catalytic Reduction (SCNR) controls to reduce nitrogen oxide emissions from the plant, which is expected to improve air quality for Colorado residents and in the Rocky Mountain National Park. The settlement was the result of allegations that modifications at the plant caused an increase in nitrogen oxide and particulate matter emissions in violation of the CAA Prevention of Significant Deterioration and Non-Attainment New Source Review requirements.

EPA Settlement to Result in Billion Dollar Sewer System Upgrade

A settlement between the federal government and Miami-Dade County in Florida announced on June 6 will result in a \$1.6 billion upgrade to the county's wastewater treatment plants and wastewater collection and transmission systems to comply with its Clean Water Act NPDES permit. The settlement followed the county's reported 211 sanitary sewer overflows that resulted in nearly 30 million gallons of raw sewage reaching waters of the United States. Miami-Dade will also pay a civil penalty of \$978,100 and complete a supplemental environmental project at a cost of over \$2 million.

FIFRA Violations Lead to Stop Sale Order

In June, EPA issued a Stop Sale, Use, or Removal Order (SSURO) to halt the sale of Antibacterial H-42 Clipper Cleaner by Georgia-based Hampton Manufacturing, Inc. EPA analysis of the product revealed that the pesticide contained less of the active ingredient than indicated on the label and the label indicated directions for use that were inconsistent with the product's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration.

Criminal Enforcement

Shipping Firms Plead Guilty to Environmental Crimes

On March 21, the U.S. Department of Justice announced that German and Cypriot shipping firms pled guilty to felony obstruction of justice charges and violating the Act to Prevent Pollution from Ships. The firms admitted that some of their ships that visited ports in California, New Jersey, and Delaware had falsified the required oil record book and had intentionally bypassed required pollution prevention equipment. The plea agreement includes a \$10.4 million penalty, some of which will go to addressing environmental damage caused by Hurricane Sandy, and a four-year probation. The probationary period will include the shipping firms, Columbia Shipmanagement GmbH and Columbia Shipmanagement Ltd., being subjected to outside audits as well as oversight by a court-appointed monitor.

Michigan Computer Company Owner Sentenced for Environmental Crimes

On March 25, Mark Glover was sentenced to 30 months in prison and fined \$10,000 for his part in trafficking in counterfeit goods and services and violating environmental laws. His company, Discount Computers, Inc. (DCI) located in Canton, Michigan, was fined \$2 million for storing and disposing of hazardous waste without a permit. The company bought and sold used computer components, often selling them for scrap. The most notable of Glover and DCI's crimes was selling used cathode ray tube monitors to countries in the Middle East and Asia. DCI would replace factory CRT labels with counterfeit labels to evade importation regulations. Older CRT monitors contain levels of lead and must be disposed of as hazardous waste.

Bio-diesel Company Owner Sentenced to Over 15 Years in Prison

Following a guilty plea entered in December 2012, Jeffrey David Gunselman was sentenced on March 29 to 188 months (15 and 2/3 years) in federal prison for counts of wire fraud, money laundering, and making false statements in violation of the Clean Air Act. Gunselman formed Absolute Fuels in Texas in 2009, which he used to defraud the EPA by "falsely representing that he was in the business of producing bio diesel fuel." Gunselman did not have a bio-diesel fuel-producing facility, but he did generate renewable fuel credits and sell those to oil companies and brokers. Gunselman received over \$41 million from companies over 51 fraudulent transactions. In addition to the prison time, Gunselman will pay \$175,000 in fines and almost \$55 million in restitution.

Illegal Rhino Horn Trader Convicted

A Chinese citizen, Shusen Wei, pled guilty in Miami on April 5 to charges regarding his involvement in the smuggling of a carved rhinoceros horn from the United States to China. Wei faces up to 10 years in prison and a fine up to \$250,000. Wei admitted to paying commissions to a Chinese national who was arrested for smuggling rhinoceros horns. The demand for and price of rhinoceros horn has risen in recent years, causing rhino populations to decline. All species of rhinoceros are protected under U.S. and international law.

Air Conditioner Thief Sentenced for Release of Ozone

On April 17, Alexander Morrisette of Monroe, Georgia was sentenced for knowingly releasing ozone-depleting substances into the environment while stealing copper and aluminum from industrial-sized air conditioning units to sell for scrap metal. He will serve 78 months in federal prison and make restitution of over \$178,800 for the repairs of the damaged air conditioners.

Salvage Company Guilty of Improper Asbestos Handling

The owners of A&E Salvage, Inc., a Tennessee salvage and demolition company, pled guilty on April 18 to one criminal felony count for conspiring to violate the "work practice standards" portion of the Clean Air Act regarding the proper wetting, stripping, bagging, and disposal of asbestos. The owners—Nick Smith and Armida and Milto Di Santi—allegedly participated in improperly removing asbestos-containing materials or illegally leaving them in place during demolition. They could face up to five years in prison and a fine of up to \$250,000.

Virginia Tech Contractor Pleads Guilty to Violation of Asbestos Regulations

On April 22, Edward K. Durst pled guilty to one count of knowingly disposing of and causing the disposal of regulated asbestos-containing materials in violation of Clean Air Act regulations during construction at Virginia Tech's Cowngill Hall. Durst's asbestos removal company was hired to remove and dispose of asbestos-containing materials, but instead disposed of the materials as ordinary scrap metal. Durst could face up to five years in prison and a \$250,000 fine.

OSHA Impersonator Sentenced to 57 Months in Federal Prison

In May, after pleading guilty to three felonies and one misdemeanor criminal charge for creating false identification documents and impersonating a federal official, Connie M. Knight was sentenced to 57 months in federal prison and ordered to pay \$25,300 in restitution. Following the Deepwater Horizon incident, Knight impersonated a high-ranking OSHA official and collected money from local fishermen for fraudulent hazardous waste cleanup courses that she alleged would assist them in obtaining jobs as part of the cleanup effort. Knight defrauded nearly 1,000 individuals many from Southeast Asian fishing communities in southern Louisiana.

Walmart to Pay Over \$110 Million for Environmental Crimes

On May 28, Walmart Stores, Inc. pled guilty in federal court to violations of the Clean Water Act (CWA) and Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for improper handling and disposal of hazardous materials and pesticides at its retail stores. Walmart will pay approximately \$81.6 million in federal criminal fines. Walmart will pay additional fines as a result of state enforcement actions in California and Missouri for a combined total of over \$110 million in environmental fines and penalties.

Agency News

EPA Finalizes Vessel Discharge Regulations

The Environmental Protection Agency issued a final vessel general permit in March that regulates discharges from commercial vessels. The intent of this permit is to protect the nation's waters from ship-borne pollutants and reduce the introduction of invasive species in U.S. waters. This new permit will replace the 2008 general permit which expires on December 19, 2013. It covers commercial vessels greater than 79 feet in length, but excludes military and recreational vessels.

EPA to Assess 23 New Chemicals Under TSCA

EPA announced in March that it will begin assessing the risks of 23 commonly-used chemicals, mainly flame-retardant chemicals, under the Toxic Substances Control Act (TSCA) Work Plan. EPA plans to study 20 flame-retardant chemicals and conduct full risk assessments for four of them. For additional information, including a list of the chemicals, go to <http://www.epa.gov/oppt/existingchemicals/pubs/2013wpractivities.html>

EPA Reminds Facilities of Hurricane Release and Reporting Requirements

In May, EPA issued a Hazardous Weather Release Prevention and Reporting alert advising facilities of requirements under various laws and regulations that require minimization and reporting of releases during hurricane events. The Clean Air Act (CAA) imposes on owners and operators a duty to prevent accidental releases of certain hazardous substances and minimize the consequences of releases that occur. The Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and the Emergency Planning and Community Right-to-Know Act (EPCRA) impose reporting obligations on owners and operators in the event of a release. According to EPA, owners and operators are required take steps before the onset of a hurricane including safely shutting down processes or utilizing emergency operations procedures in order to prevent releases. A copy of the alert is available at http://www.epa.gov/region4/r4_hurricanereleases.html.

Formaldehyde Regulations Proposed by EPA

In May, EPA proposed two rules to protect against formaldehyde exposure in accordance with the 2010 Formaldehyde Standards for Composite Wood Products Act (Title VI of the Toxic Substances Control Act), which limits emissions of formaldehyde from composite wood products. One rule would limit formaldehyde emissions and establish testing, labeling, and recordkeeping requirements. The other establishes a third-party certification program to ensure that manufacturers meet emission standards. For more information go to <http://www.epa.gov/oppt/chemtest/formaldehyde/index.html>.

Biotechnology News

Supreme Court Addresses Patent Exhaustion in Roundup Ready Seeds Case

In *Bowman v. Monsanto*, decided on May 13, the U.S. Supreme Court held that the patent exhaustion doctrine, which gives the purchaser or subsequent owner of a patented article a right to use or resell the article, did not allow a farmer to make new copies of the patented invention without the patent holder's permission. *See* 133 S. Ct. 1761 (2013). The Court thereby affirmed the lower court's award of \$84,456 in damages to Monsanto Company based on Indiana farmer, Vernon Bowman's, purchase of "commodity soybeans" intended for human or animal consumption that came from prior harvests of local farmers, most of whom used Roundup Ready patented seeds. Bowman planted these soybeans, saved the seeds from the crop, and re-used them for planting the following years. The Court held that although Bowman could resell the patented soybeans he purchased, consume the beans, or feed the beans to his animals, he could not make additional copies of the seed without infringing on Monsanto's patent.

Miscellaneous

Bipartisan Bill Introduced to Improve Chemical Safety

The Lautenberg-Vitter "Chemical Safety Improvement Act of 2013," which was introduced by the late Sen. Frank Lautenberg (D-N.J.) and Sen. David Vitter (R-La.), would modernize the Toxic Substances Control Act (TSCA) by requiring that all active chemicals in commerce be evaluated based on their risks to the environment and human health. All chemicals would be deemed "high" or "low" priority with high priority chemicals undergoing further review. The bill would also provide the agency with greater access to chemical information and flexibility on the necessary action to take regarding chemicals deemed unsafe. A copy of the bill is available at <http://cen.acs.org/content/dam/cen/91/web/S-1009-113th-Congress.pdf>.

ATTORNEY PROFILES

Richard E. Davis is a senior partner with Starnes Davis Florie LLP. He represents clients in federal and state courts in Alabama as well as in matters involving federal and state regulatory agencies. Richard's environmental practice includes Clean Water Act, Clean Air Act, and CERCLA litigation; natural resource and property damage claims; land use and water use issues; and the defense of corporations and individuals accused of environmental crimes as well as regulatory enforcement and compliance matters. Richard also defends personal injury actions based on alleged chemical exposure (so-called "toxic torts"). Richard is a Fellow in the Litigation Counsel of America Trial Lawyer Honorary; was listed in the 2008 - 2012 editions of *Alabama Super Lawyers*[®] magazine for Environmental Litigation, was selected for inclusion in the 2011, 2012, and 2013 editions of *Best Lawyers in America*[®]—in 2011 for both Environmental Law and Natural Resources Law and in 2012 and 2013 for both Litigation-Environmental and Natural Resources Law; was included by ALM (publisher of *The American Lawyer*, *Corporate Counsel*, and law.com) as a Top Rated-AV Preeminent Lawyer in Mass Tort Litigation; was selected by peer review as one of Birmingham Magazine's Top Attorneys in Environmental Law in 2012; and served as Chair of the Alabama State Bar Environmental Law Section for 2010-2011.

J. Scott Dickens is a partner with Starnes Davis Florie LLP. Scott's practice is primarily devoted to environmental and construction litigation. He has represented clients in all State and Federal Courts in Alabama, in arbitration proceedings before the American Arbitration Association and Alabama Building Commission, and in the United States Court of Federal Claims. Scott's practice includes CERCLA and RCRA litigation; architect and engineer liability claims, particularly relating to environmental issues; and construction related matters. He also frequently speaks at environmental and construction seminars. Scott is a 1996 graduate of Cumberland School of Law where he was a member of the *Cumberland Law Review*.

Amber M. Whillock is an associate with Starnes Davis Florie LLP. Amber's practice is primarily devoted to environmental litigation and regulatory compliance and includes defense of Clean Water Act and Clean Air Act claims; litigation of Comprehensive Environmental Response, Compensation, and Liability Act Contribution and cost recovery claims; defense of common law property damage claims; and defense of personal injury claims based on exposure to chemicals and other pollutants. While attending Cumberland School of Law, Amber was the Executive Editor of the *Cumberland Law Review*, a Thomley Scholarship Recipient, a George M. Stewart Banking Award Recipient and the recipient of numerous Scholar of Merit Awards.

OFFICE LOCATIONS

Birmingham

Tele: (205) 868 • 6000
100 Brookwood Place
7th Floor
Birmingham, AL 35209

Mobile

Tele: (251) 433 • 6049
RSA-Battle House Tower
11 North Water Street
20th Floor
Mobile, AL 36602

starneslaw.com

The Alabama Rules of Professional Conduct require the following statement: *No representation is made that the quality of the legal services to be performed is greater than the quality of legal services performed by other lawyers.*

This bulletin, and all the content it contains, was created by attorneys of Starnes Davis Florie LLP. The content of this bulletin does not convey legal advice, nor other professional advice of any kind. Your use of this bulletin does not create a lawyer-client relationship between you and the Firm.

©June 2013, Starnes Davis Florie LLP