Texas Environmental Update

BEVERIDGE & DIAMOND PC

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Texas Developments

TCEQ Work Session Addresses Enforcement & Penalty Policies

On September 28, 2011, the Texas Commission on Environmental Quality ("TCEQ") commissioners conducted a work session regarding four aspects of implementing the 2011 TCEQ Sunset Bill (HB 2694). The commissioners voted to amend TCEQ's Penalty Policy consistent with staff recommendations based on discussion at the commissioners' last work session in August. Regarding enforcement policy, staff reported on public input the agency received in written comment letters and at an August 25, 2011 stakeholder meeting regarding adoption of a general enforcement policy rule. Development of such a policy is scheduled to be discussed at a work session in November. The Executive Director plans to present a proposed enforcement policy rule for consideration at the March 28, 2012 commissioners' agenda meeting. The commissioners also discussed local governments' use of Supplemental Environmental Projects ("SEPs") and the Watermaster Evaluation Process. The work session agenda and back-up documents are available on TCEQ's website at http://www.tceq.texas.gov/assets/public/comm_exec/agendas/worksess/current/2011/092811.pdf.

Texas Hydraulic Fracturing Disclosure Rule Proposed

On September 9, 2011, the Texas Railroad Commission ("Commission") published a proposed Hydraulic Fracturing Chemical Disclosure Requirements rule to implement Texas Natural Resources Code Section 91.851, as enacted by House Bill 3328 (82nd Legislature (Regular Session, 2011)). The proposed rule would require oil and gas well operators to disclose information about the chemical ingredients and volume of water used in hydraulic fracturing, with specified protections for trade secrets. Information would be disclosed by entry into the "FracFocus" hydraulic fracturing chemical registry website of the Ground Water Protection Council and the Interstate Oil and Gas Compact Commission. The disclosure requirement will apply to hydraulic fracturing performed in Texas for which an initial drilling permit is issued on or after the effective date of the rule. The Commission will conduct a public hearing on the proposed rule in Austin on October 5, 2011. The public comment period ends on October 11, 2011. The proposed rule is available on the Commission's website at http://www.rrc.state.tx.us/rules/proposed.php.

State of Texas Sues to Stay CAIR Rules

The State of Texas has challenged and requested a partial stay of the final Clean Air Interstate Rule ("CAIR") applicable to Texas. *Texas v. EPA*, D.C. Cir. (September 22, 2011). The petition of the State claims that the CAIR illegally deviated from the proposed rule without adequate notice and opportunity for comment and will impose overreaching substantive controls that will cause job losses in Texas. The State of Kansas filed a similar challenge. The Rule is designed to reduce interstate transport of sulfur dioxide and nitrogen oxides, implementing the "good-neighbor" provisions of the Clean Air Act (42 U.S.C.§ 7410(a)(2)(D)(i)(I)). The Texas Attorney General's news release on this action, with links to the motion to stay and petition for review, is available at https://www.oag.state.tx.us/oagNews/release.php?id=3857.

River Authority To Seek To Deny Farmers Water Due to Severe Drought

On September 21, 2011, the Board of the Texas Lower Colorado River Authority ("LCRA") authorized the agency to seek permission from TCEQ to deviate from its Water Management Plan for Lake Travis and Lake Buchanan to cut off or significantly reduce water to farmers in three Gulf Coast counties: Colorado, Wharton and Matagorda. The severe drought throughout the state is hitting record-setting levels. Texas is experiencing its driest eleven-month period since the State began keeping rainfall records in 1895 and the hottest summer in the nation's history. Additional information about the decision is available at http://www.lcra.org/newsstory/2011/boardadoptsdroughtreliefmeasures.html.

EPA Proposal on Texas Infrastructure & Interstate Transport SIP Submittals

On September 22, 2011, EPA published a proposed rule (available at www.bdlaw.com/assets/attachments/Proposed%20partial%20approval%20and%20partial%20disapproval%20of%20TX%20SIP%2076%20FR%2058748.pdf to partially approve and partially disapprove Texas state implementation plan ("SIP") submittals that address infrastructure elements to implement, maintain, and enforce the 1997 eight-hour ozone and 1997 and 2006 fine particulate matter national ambient air quality standards ("NAAQS"). EPA is proposing to find that the Texas SIP does not meet specified federal Clean Air Act ("FCAA") infrastructure requirements for the referenced standards because Texas has stated it cannot issue permits for and does not intend to regulate greenhouse gas ("GHG") emissions. The proposal also includes partial approval and partial disapproval of Texas SIP revision submittals regarding the FCAA ``good neighbor'' provisions for the referenced standards, addressing the requirement to have adequate provisions to prevent air emissions from adversely affecting another state's air quality by interstate transport. Along with partial approval, partial disapproval is proposed for SIP submittals regarding the requirement that emissions from Texas sources not interfere with measures required in the SIP of any other state, because Texas has stated it cannot issue permits for GHG emissions. EPA is also proposing approval of SIP revisions for Prevention of Significant Deterioration to include nitrogen oxides ("NOx") as an ozone precursor. Comments on the proposed rule must be submitted to EPA by October 24, 2011.

TCEQ Publishes State Superfund Registry

TCEQ has issued its annual revision of lists of sites under the State Superfund registry in accordance with the Texas Solid Waste Disposal Act. Based on hazard ranking system ("HSR") scores, the Commission listed as State Superfund Sites twenty-six new facilities that it determined pose an imminent and substantial endangerment to the environment due to a release or threatened release of hazardous substances. The Commission also proposed to add twenty-four new facilities to the registry that may pose such an endangerment. The Commission also delisted forty-seven sites. The lists of sites are available at http://www.tceq.texas.gov/remediation/superfund/registry.html and were published at 36 Tex. Reg. 6307, 6314-15 (September 23, 2011).

Upcoming TCEQ Meetings and Events

- TCEQ will host its annual ***Advanced Air Permitting Seminar and an Oil and Gas Facilities Workshop*** in Austin on October 26 and 27, 2011. Information regarding these events is available at http://www.tceq.texas.gov/p2/events/AdvancedAirPermitting.

- In partnership with UT-Arlington's Zero Waste Network, TCEQ will host ***Pollution Prevention Workshops*** in Fort Worth on October 4-5, 2011, and in Houston on December 6-7, 2011. These workshops provide information about designing and implementing effective, cost-saving pollution prevention plans that comply with the Texas Waste Reduction Policy Act rules (30 TAC §335.471-§335.480). Additional information about these workshops is available at http://www.zerowastenetwork.org/workshops/index.cfm.

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TCEQ Enforcement Orders

TCEQ announcements for enforcement orders adopted in September can be found on the TCEQ website at www.tceq.texas.gov/news/releases/092111commissionersagenda.

Recent Texas Rules Updates

For information on recent TCEQ rule developments, please see the TCEQ website at http://www.tceq.state.tx.us/rules/whatsnew.html.

National Developments

EPA Proposes New Efficacy Test Guidelines for Public Health Antimicrobial Products

On September 15, 2011, the U.S. Environmental Protection Agency ("EPA") made available for public comment a series of new draft efficacy test guidelines under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") for antimicrobial pesticides that bear public health claims. 76 Fed. Reg. 57031 (Sept. 15, 2011), available at http://www.bdlaw.com/assets/attachments/EPA%20Antimicrobials%20Efficacy%2075%20Fed%20Reg%2057031.pdf. Comments on the proposed guidelines must be received by EPA before December 14, 2011.

Unless otherwise exempted from regulation under FIFRA, products that make antimicrobial claims (which include claims to reduce or mitigate the growth of microbiological organisms, as well as claims to protect surfaces, processes, or water against contamination caused by bacteria, viruses, fungi, protozoa, algae, or slime) are considered pesticides that must be registered by EPA before they may be sold or distributed in the United States. While EPA requires applicants to develop efficacy (i.e., product performance) data to support claims made for all antimicrobial and other pesticide products, EPA generally only requires the submission of efficacy studies from applicants that make public health claims in connection with their products. 40 C.F.R. § 400(e)(1).

"Public health" antimicrobial products generally include those intended for use as sterilizers, disinfectants, or sanitizers on environmental surfaces.[1] In 2010, EPA made draft efficacy test guidelines available for sterilants, hard surface disinfectants, and hard surface sanitizers. 75 Fed. Reg. 4380 (Jan. 27, 2010). Those products subject to EPA's newly published draft test guidelines include:

- water sanitizers, such as: (a) solutions, powders, or tablets intended for emergency disinfection of small quantities of drinking water of questionable potability; (b) products bearing claims for microbiological drinking water purification; and (c) disinfectants intended for use in swimming pools, spas, and hot tubs;
- air sanitizers intended for use in residential, commercial, industrial, hospital and medical environments (expressly including air sanitizers that contain at least 5% glycol); and
- fabric and textile disinfectants and sanitizers, such as: (a) laundry additive products intended for antimicrobial use in the pre-soak treatment of laundry or in household, hospital, or commercial laundry; (b) laundry additive products which bear claims to provide "residual" self-sanitizing activity on treated fabrics after use in automatic washing machines; (c) products intended for use as carpet sanitizers; (d) antimicrobial products used to treat mattresses, pillows, and upholstered furniture; and (e) fabric and textile surface sanitizer products.

The new draft guidelines describe test methods and procedures that will, according to EPA, "generally satisfy testing requirements" of FIFRA and the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Once final, EPA intends to incorporate these test guidelines into EPA's data requirements for antimicrobial products, proposed by EPA on October 8, 2008. In addition, EPA notes that these draft test guidelines may be incorporated into future regulatory actions

taken by EPA under the Toxic Substances Control Act ("TSCA").

For more information about EPA's proposed test guidelines or registration requirements for antimicrobial products more generally, please contact Kathy Szmuszkovicz at Beveridge & Diamond, P.C. (kes@bdlaw.com or 202-789-6037) or Alan Sachs, Independent Consultant Attorney (ajs@bdlaw.com or 410-230-1345). For more information about EPA's pending proposal to revise the data requirements for antimicrobial products more generally, please see B&D's November 10, 2008 Alert, "EPA Proposes New Data Requirements for Antimicrobial Products," available at http://www.bdlaw.com/news-409.html.

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[1] Sterilization claims made in connection with critical and semi-critical medical devices are separately regulated by the U.S. Food and Drug Administration ("FDA") and excluded from regulation under FIFRA. 40 C.F.R. § 152.6(a).

Pharmaceuticals Stewardship Legislation Introduced in Congress

On September 15, 2011, Representative Slaughter (D, NY) introduced the Pharmaceutical Stewardship Act of 2011 ("The Act") (H.R. 2939),[1] which would create a national, producer-funded pharmaceuticals take-back program. The Act would create a National Pharmaceutical Stewardship Organization and require manufacturers and brand owners of drugs marketed in the United States to participate in a certified pharmaceuticals stewardship program. Product stewardship programs aim to provide convenient disposal alternatives that are protective of the environment and public health and safety. Programs would need to be implemented within two years of the bill's enactment.

Proposed Scope

The Act would impose stewardship requirements on manufacturers and brand owners of drugs marketed in the United States. The term "manufacturer" is not defined, but the Act defines "brand owner" to mean "the holder of an approved application for the drug under section 505 of the Federal Food Drug and Cosmetic Act (21 U.S.C. 355)."

The Act would apply to controlled and uncontrolled substances. The term "drug" has the same meaning as in the Federal Food Drug and Cosmetic Act (FDCA),[2] but the Act would exempt drugs for which a take-back program is already in effect under FDCA § 505-1.

Creation of a National Pharmaceutical Stewardship Organization

The Act would establish the National Pharmaceutical Stewardship Organization ("Organization"), a private nonprofit corporation, and task the Organization with implementing a national pharmaceutical stewardship program. The organization's board of directors would include industry and public health representatives.

National Certified Pharmaceutical Stewardship Programs

The Act would require the Organization to submit an application for a national product stewardship program to the U.S. Environmental Protection Agency (EPA). EPA may certify the program if it meets criteria identified in the Act, including:

- Participating manufacturers and brand owners fully pay the costs of the program; which would be allocated among manufacturers according to market share;
- The program is developed with public input;
- The program accepts drugs that are delivered by individuals and are household wastes;
- Collected drugs are incinerated in accordance with hazardous waste incineration requirements (EPA may approve alternative disposal technologies upon petition);
- The program includes at least one collection site in every county of every state and every city with 10,000 or more people, or, where that is not feasible, the system provides prepaid mailing envelopes;

- Controlled substances are collected and disposed of in a manner consistent with § 302(g) Controlled Substances Act (CSA); and
- The program meets specific education and outreach requirements.

The Organization would be required to renew the program certification every four years.

Under the Act, drug manufacturers and brand owners may jointly or individually seek certification for a separate national pharmaceutical stewardship program that meets the criteria described above. Certification for such programs would have to be renewed every three years.

Certified programs would be required to submit annual reports to EPA, including information on the weight of drugs collected, any safety or security problems that occurred, the program's total expenditures, and a description of packaging material recycling. These reports would be made available to the public. In addition, the Act would require certified programs to annually invite public comment on the services provided, share that information with EPA, and use the comments to inform program updates.

Penalties, Program Suspension, and State and Local Laws

The Act authorizes civil penalties of up to $50,000 per day in instances where an obligated manufacturer or brand owner does not participate in a certified program or violates its obligations to contribute to a program's costs. The Act would also authorize EPA to suspend the certification of any national program to protect the public from imminent danger. States, tribes, and local governments could adopt more stringent drug disposal requirements.

Commission & Report by the Comptroller General

The Act would require EPA to establish an interagency Commission on Drug Disposal and Its Public Safety, Public Health, and Environmental Impacts ("the Commission").[3] The Commission is tasked with development of a strategy to prevent drugs from entering the water supply and environment and to reduce diversion and the risk of abuse and accidental overdose. The Commission would be required to submit a strategy to Congress within two years of the law's enactment and annually thereafter. The strategy must assess the risks and identify strategies for reducing risks associated with misuse of prescription drugs, address sources of contamination, and make recommendations on minimum environmental standards for disposing of drugs. The strategy would be designed to inform EPA regulations and guidance on these issues.

Finally, the Act would require the U.S. Comptroller General to submit a report to Congress on drugs and drug byproducts in surface and groundwater in the United States. The report would be required to include recommendations for government actions to prevent entry of drugs and byproducts into the water supply and identify areas of additional research.

Existing Legal Landscape

The proposed law would enact the United States' first mandatory producer responsibility program for pharmaceuticals. The issue of pharmaceutical take-back has been considered at the state level and peripherally at the federal level for some time.

In October 2010, Congress enacted the Secure & Responsible Drug Disposal Act, amending § 302(g) of the Controlled Substances Act. The law allows an ultimate user to deliver a controlled substance to an authorized person for disposal in accordance with forthcoming regulations.[4] Pub. L. 111-273 § 3(a), 124 Stat. 2859 (Oct. 12, 2010), amending 21 U.S.C. § 822(g). While DEA has held a listening session, it has not yet proposed a rule identifying the specific requirements for delivery and disposal of controlled substances under § 302(g).

Meanwhile, EPA proposed a rule in 2008 that would add hazardous pharmaceutical wastes to the Universal Waste Rule. 73 Fed. Reg. 73,520 (Dec. 2, 2008). The Universal Waste Rule streamlines hazardous waste collection requirements for specified wastes. EPA believes the designation of pharmaceuticals as universal wastes would remove barriers to the collection of pharmaceutical wastes and facilitate take-back programs. *Id*. EPA

extended the comment period on the rule in 2009, but there has been no further action to date. EPA has indicated that it has no projected date for finalizing the rule.

A number of states have engaged in pilot take-back programs (e.g., Maine, Iowa), but no state has imposed mandatory take-back obligations on manufacturers. In 2011 several states considered, but did not pass, legislation that would have created mandatory producer take-back programs. New York bills would have required all drug manufacturers to establish and implement take-back programs (AO 4651, AO 211/SO 0830). In Washington, S.B. 5234/H.B. 1370 would have a manufacturer-funded and –managed product stewardship organization for the statewide collection and disposal of controlled and uncontrolled substances from residential sources. The California Department of Resources Recycling and Recovery (CalRecycle) has recommended the state legislature enact legislation to create a privately financed pharmaceutical stewardship program. Recommendations for Home-Generated Pharmaceutical Collection Programs (Dec. 2010). At the local level in California, the city of San Francisco considered an ordinance in May 2011 that would have imposed producer responsibility requirements on drug manufacturers that sell their products in the city. Industry funded a pilot program in the city and the ordinance was reformulated to require informational materials at retail outlets. Safe Drug Disposal Information Ordinance 85-11.

In Canada, there is no federal program that imposes stewardship requirements for pharmaceuticals, but several provinces have addressed the issue. British Columbia, Manitoba, and Ontario have enacted regulations that require manufacturer-financed take-back programs for pharmaceuticals. All three provinces utilize a pharmaceutical stewardship organization to develop and implement the programs.

For more information, please contact Paul Hagen (202.789.6022, phagen@bdlaw.com), Jennifer Abdella (301.481.0811, jabdella@bdlaw.com), or Bina Reddy (202.789.6082, breddy@bdlaw.com).

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[1] A copy of the Act is available at www.govtrack.us/congress/bill.xpd?bill=h112-2939.

[2] The FDCA defines drugs as "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement." 21 U.S.C. § 321(g)(1)

[3] The Commission would consist of representatives from EPA, the Centers for Disease Control and Prevention, the National Institute of Environmental Health Sciences, the Drug Enforcement Administration, the Food and Drug Administration, Veterans Affairs, the Centers for Medicare and Medicaid Services, the National Drug Control Policy, and any other federal official with relevant expertise appointed or invited by EPA, individuals with expertise in public health, public safety, or the environment appointed by EPA, and state and local officials invited by EPA. The Commission would terminate five years after enactment of the Pharmaceutical Stewardship Act.

[4] The Pharmaceutical Stewardship Act would require pharmaceutical stewardship organizations to manage controlled substances in a compliance with § 302(g).

EPA, Industry Propose New Prioritization Scheme for Chemicals of Concern

As part of its efforts to "enhance" management of chemicals under its current Toxic Substances Control Act ("TSCA") authority, EPA is shifting from its "Chemical Action Plans" to a new program for identifying priority chemicals. While the Chemical Action Plans will continue to be operative for the chemicals for which they have already been issued,[1] EPA announced in mid-August that it is seeking comment on a new approach to chemical prioritization.[2]

As a mechanism for gathering input from stakeholders and the public on the new approach, EPA held a well-attended webinar and lively discussion forum on September 7, 2011. It has also opened an online discussion forum, which will remain open for comment through September 14, 2011.[3] A number of comments have already been added. Once the online discussion forum closes, EPA will place discussion forum comments to http://www.regulations.gov docket EPA-HQ-OPPT-2011-0516. At the webinar, the Director of the Office of Pollution Prevention and Toxics, Wendy Cleland-Hamnett, indicated that the prioritization process will be implemented and a first slate of chemicals will be identified by the end of 2011.

EPA's Discussion Guide identifies a two-step process. First, in Step 1, EPA will identify an initial group of roughly a few hundred priority chemicals for review by using a specific set of data sources to identify chemicals that meet the priority factors. EPA has tentatively identified the following prioritization factors:

- Chemicals identified as potentially of concern for children's health (e.g., chemicals with reproductive or developmental effects).
- Chemicals identified as persistent, bioaccumulative, and toxic (PBT).
- Chemicals identified as probable or known carcinogens.
- Chemicals used in children's products.
- Chemicals used in consumer products.
- Chemicals detected in biomonitoring programs.

EPA is also seeking comment on potential data sources, which include such sources as EPA's own data (e.g. Toxic Release Inventory, Integrated Risk Information System) and data and designations from other federal and state agencies. However, EPA's Tox21 and ToxCast scientific initiatives, which are specifically oriented toward screening and prioritization of chemicals, are not mentioned. Moreover, except for Canada's categorization of chemicals under the Canadian Environmental Protection Act 1999, there is rather little attention to chemicals categorization outside the United States, even in the European Union which has been implementing its Regulation on Evaluation, Authorization, and Restriction of Chemical Substances (REACH) for several years. Webinar and online comments appear already divided with respect to the degree to which Canada's program, in particular, should be a model or a data source.

The second step would further narrow the set of chemicals based on additional exposure and hazard data sources for further assessment and possible risk management action. EPA is seeking comment on the data sources for Step 2, as well as any other relevant program elements.

Among the comments provided at the webinar and on the online discussion forum were references to an industry-led prioritization program initiative intended as a supplement to EPA's proposal. The American Chemistry Council ("ACC") released its more detailed prioritization tool the day before EPA's webinar.[4] ACC's approach would screen chemicals first on the basis of enumerated human health and environmental hazard potential and exposure potential criteria to arrive at initial overall priority groupings. Second tier considerations within priority groupings would then factor in, for example, biomonitoring data and use in children's products (which in EPA's approach are used in Step 1).

For more information on approaches to prioritization of chemicals under TSCA, please contact Mark Duvall, 202-789-6090, mduvall@bdlaw.com, or Andie Wyatt, 202-789-6086, awyatt@bdlaw.com.

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1 See Beveridge & Diamond, P.C., TSCA Developments in Congress and at EPA (Aug. 11, 2011), http://www.bdlaw.com/news-1193.html; EPA, Existing Chemical Action Plans, http://www.epa.gov/oppt/existingchemicals/pubs/ecactionpln.html.

2 EPA, Identifying Priority Chemicals for Review, http://www.epa.gov/oppt/existingchemicals/pubs/chemprioritizations.html.

3 EPA, Discussion Forum: Identifying Priority Chemicals for Review and Assessment, http://blog.epa.gov/chemprioritization/.

4 ACC Press Release, ACC Proposes New System to Prioritize Chemicals for Review; Transparent and Scientifically-Sound Process is Key to Successfully Updating TSCA (Sep. 7, 2011), http://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Proposes-New-System-to-Prioritize-Chemicals-for-Review.html. The briefing document for ACC's prioritization tool is available at http://www.americanchemistry.com/Prioritization-Document.

Firm News & Events

Beveridge & Diamond Wins Reversal of Abstention Ruling in Ninth Circuit

Litigators from Beveridge & Diamond. P.C.'s Washington and San Francisco offices secured a unanimous decision from a Ninth Circuit panel reversing a District Court decision that Younger abstention required dismissal of a Commerce Clause challenge to a local voter initiative.

In a published decision (available at http://www.bdlaw.com/assets/attachments/Potrero%20Hills%20v.%20County%20of%20Solano%209th%20Circuit%20Opinion.pdf), the Ninth Circuit held that a pending mandamus action in state court that sought to enforce the voter initiative was not a state interest that warranted a federal court abstaining from hearing a challenge to the voter initiative. The panel wrote that the case "provides us a much-needed opportunity to clarify the scope of what constitutes an important state interest" for Younger abstention by a federal court from hearing a case over which it otherwise has jurisdiction.

Jimmy Slaughter, a Principal in the Firm's Washington office who argued the case, is quoted in a BNA Daily Environment Report article about the decision, Ninth Circuit Remands Case on Restriction Of Trash Imports to Landfill in California.

To read the article, please go to http://www.bdlaw.com/assets/attachments/BNA%20Inc%20DER%20-%20Ninth%20Circuit%20Remands%20Case%20on%20Restriction%20of%20Trash%20Imports%20to%20CA.pdf. *Reproduced with permission from Daily Environment Report, 179 DEN A-9 (Sep. 15, 2011). Copyright 2011 by The Bureau of National Affairs, Inc. (800-372-1033) http://www.bna.com*

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