Massachusetts Environmental and Land Use Alert

BEVERIDGE & DIAMOND PC

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Massachusetts Environmental Developments

Mass DEP Releases Air Permitting Guidance Documents

As part of its announced effort to streamline air permitting, the Massachusetts Department of Environmental Protection (Mass DEP) has released a number of helpful and substantive air permitting guidance documents for use by the regulated community in preparing permit applications for air emission sources. *(full article)*

Changes to MassDEP Audit Target under Chapter 21E

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The Massachusetts Land Court has held that a variance is effective even if it is recorded outside the statutory one-year period so long as there has been substantial reliance on it. (*full article*)

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The Massachusetts Appeals Court has ruled that a subdivision approval condition requiring the dedication of open space for public use and actual conveyance of that open space to the town in exchange for certain waivers without just compensation violates the Subdivision Control Act. (*full article*)

National Developments

U.S. EPA Issues Guidance on Enforcement Discretion for the "Affiliation" Criterion of the "Bona Fide Prospective Purchaser" Defense

On September 21, 2011, U.S. EPA issued guidance to its Regional Counsel regarding the "affiliation" criterion that owners must meet in order to be considered a "bona fide prospective purchasers" (BFPP) under CERCLA. *(full article)*

TSCA Developments in Congress and at EPA

Legislation to amend the Toxic Substances Control Act is still in play, despite the Congressional preoccupation with other issues. EPA is making considerable progress in implementing its Enhanced Chemical Management Program under TSCA, despite roadblocks set up by the Office of Management and Budget. *(full article)*

California Releases Latest Versions of GHG Cap and Trade and Reporting Programs

The California Air Resources Board (CARB) has released the latest version of its greenhouse gas ("GHG") cap and trade regulation: the "California Cap on Greenhouse Gas Emissions and Market-Based Compliance Mechanism." *(full article)*

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On September 15, 2011, Representative Slaughter (D, NY) introduced the Pharmaceutical Stewardship Act of 2011 (H.R. 2939), which would create a national, producer-funded pharmaceuticals take-back program. *(full article)*

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. *(full article)*

Beveridge & Diamond Named to National Law Journal's 2011 Midsize Hotlist

The National Law Journal has named Beveridge & Diamond, P.C. to its "2011 Midsize Hotlist." The list, released on July 11, recognizes twenty law firms in the 50- to 150-lawyer range around the country that have "proven they can continue to thrive in this troubled economy." *(full article)*

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Massachusetts Environmental Developments

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As part of its announced effort to streamline air permitting, the Massachusetts Department of Environmental Protection (Mass DEP) has released a number of helpful and substantive air permitting guidance documents for use by the regulated community in preparing permit applications for air emission sources. These guidance documents provide useful direction and examples from Mass DEP to simplify and – to some extent – demystify, the air permitting process. The guidance is available from Mass DEP's web site as follows:

- **Plan Approval Overview and Applicability Table**
  http://www.mass.gov/dep/air/approvals/aqpaguid.pdf
  Provides guidance on sources that can use the permits-by-rule process, sources that can use the alternative environmental results program, and thresholds for permitting of certain combustion units.

- **Best Available Control Technology Guidance**
  http://www.mass.gov/dep/air/approvals/bactguid.pdf
  Provides general guidance on state BACT requirements including when you can use presumptive BACT and how Mass DEP implements the Top-Down BACT review. In reviewing this document, it is important to keep in mind that the methodology used to determine state BACT is different from federal BACT.

- **Top Case BACT Guidelines for Combustion Sources**
  http://www.mass.gov/dep/air/approvals/bactcmb.pdf
  As a companion to the general BACT guidance, this document provides specific examples of Mass DEP's top case BACT determinations for specific types of combustion sources (boilers, incinerators, biomass steam electric generation units, reciprocating internal combustion engines, and combustion turbines) as of June 2011.

- **Top Case BACT Guidelines for VOC Sources**
  http://www.mass.gov/dep/air/approvals/bactvoc.pdf
  As a companion to the general BACT guidance, this document provides specific examples of Mass DEP's top case BACT determinations for eleven categories of VOC sources (printing, painting, VOC coating, miscellaneous, cleaning and degreasing, expandable polystyrene, bulk gasoline terminals and storage tanks, biotech disinfection, and chemical and coating manufacturing) as of June 2011.

- **Top Case BACT Guidelines for Mechanical and Miscellaneous Sources**
  http://www.mass.gov/dep/air/approvals/bactmech.pdf
  As a companion to the general BACT guidance, this document provides specific examples of Mass DEP's top case BACT determinations for eleven categories of miscellaneous sources (ammonia storage and handling, asphalt processing and roofing, bulk cement ship unloading, concrete batch plants, dry bulk material handling and unloading, material and coal handling, rock crushing, hot mix asphalt, chrome plating and anodizing, ethylene oxide sterilization, and galvanizing operations) as of June 2011.

For further information on Mass DEP air permitting, please contact Stephen Richmond at srichmond@bdlaw.com or Jeanine Grachuk at jgrachuk@bdlaw.com.

Changes to MassDEP Audit Target under Chapter 21E

Under the Massachusetts notification and cleanup law for releases of oil or hazardous material, Chapter 21E, Licensed Site Professionals (LSPs) are empowered to make site assessment and cleanup decisions for most sites, subject to audit by the Massachusetts Department of Environmental Protection (Mass DEP). To ensure compliance with Chapter 21E, and its implementing regulations known as the MCP, Mass DEP was

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required by statute to audit 100% of those sites with institutional controls, generally sites with activity and use limitations (AULs), and to audit 20% of all sites.

Effective July 1, 2011, the audit target for all sites including sites with AULs has changed to "a statistically significant number," which is to be determined by Mass DEP based on "the need for audits to ensure a high level of compliance ... and the need to target audit resources in the most efficient and effective manner." This means that Mass DEP will be able to set its own auditing goal. While it is not yet clear whether fewer sites will be audited under this provision, it does provide Mass DEP with additional flexibility at a time of limited resources.

For further information on site cleanup in Massachusetts, please contact Jeanine Grachuk at jgrachuk@bdlaw.com.

Comprehensive Review of Regional Greenhouse Gas Initiative To Be Conducted

The Regional Greenhouse Gas Initiative ("RGGI"), the first mandatory cap-and-trade program to reduce greenhouse gas ("GHG") emissions from fossil fuel-fired generators, aims to cap GHG emissions from the power sector and reduce those emissions by ten percent of baseline emissions by no later than 2018.

To accomplish this, the Northeastern and Mid-Atlantic states participating in RGGI signed a Memorandum of Understanding ("MOU") starting in 2005 that established regional and state-level emissions limits for electric generators. Each participating state then adopted regulations to implement the commitments in the MOU. Ten states originally joined the compact, although one - New Jersey - has recently withdrawn.

Regulated emitters in participating states must provide emission allowances or, to a limited extent, offsets for every ton of regulated GHGs that they emit. These allowances are nearly all sold through quarterly auctions, which include a floor price to assure a minimum clearing price for the allowances, and the revenues are distributed to the participating states. RGGI allowances at recent auctions have cleared at the lowest allowable price, and trading on the secondary market has been weak.

The RGGI MOU requires the participating states to perform a comprehensive review of all components of the program in 2012. Because of the breadth of the comprehensive review called for by the MOU, the process may address issues that have the potential to impact businesses and organizations beyond the electric generators directly subject to the RGGI regulations. Issues that the participating states will examine include: RGGI's success to date in cutting GHG emissions; the program's impact on energy prices and the reliability of the electric system; the option of expanding emission reduction objectives; whether there has been emissions leakage; and the use of offsets.

Preliminary modeling performed for RGGI indicates that, under the majority of scenarios analyzed, the GHG emissions within the regulated region will remain well below the emissions cap, which would put a damper on allowance prices and limit the amount of money raised by participating states from the sale of emission allowances. Decisions about the future of RGGI, such as how to allocate future or unsold emission allowances, whether to change the reserve price at which allowances are sold, or whether to lower the emissions cap, could have far-reaching impacts, including on electricity prices in the region, the financial viability of alternative energy projects and the market for offset credits.

In preparation for this comprehensive review, participating states are, in coordination with RGGI Inc., a non-profit corporation created by the participating states to support development and implementation of RGGI, is holding stakeholder meetings and soliciting comments from interested parties. Meeting materials and stakeholder comments submitted to date are available at http://www.rggi.org/design/program_review.

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For fossil fuel-fired electric generators that are currently regulated by RGGI-implementing regulations, there will also be a free webinar on the RGGI compliance process on October 4, 2011, from 1 – 3 p.m., EST. The first control period in the RGGI Budget Trading Program ends on December 31, 2011 and the deadline for regulated power plants to provide emission allowances for compliance and to certify compliance for the first control period is the end of March 1, 2012. Information about the webinar, which will include an overview of the compliance process and an opportunity for questions, is available at http://www.rggi.org.

For more information on RGGI or climate change initiatives, please contact Stephen Richmond, srichmond@bdlaw.com, or Aladdine Joroff, ajoroff@bdlaw.com.

Massachusetts Land Use Developments

Municipality Cannot Require Variance for Extension of Residential Non-Conformity

Homeowners wishing to extend or expand their pre-existing non-conforming single- or two-family residential structures cannot be forced by a municipality to obtain anything other than a Special Permit under M.G.L. c. 40A, § 6, the Massachusetts Supreme Judicial Court ruled in *Gale v. Zoning Board of Appeals of Gloucester*, 2011 Mass. App. LEXIS 1154, Docket No. 10-P-1536 (September 2, 2011).

In what appears to be all too common in land use cases that make it to Massachusetts's highest court, the dispute arises out of a parcel of land with water views that was divided between two siblings whose descendents no longer get along. When one branch of the family decided to replace a pre-existing, non-conforming seasonal cottage with a larger year-round residence, they sought a Special Permit under M.G.L. c. 40A, § 6. They also applied for a variance under Gloucester's zoning ordinance, which requires that unless authorized by a variance from the Zoning Board of Appeals, "those portions of the replacement structure that constitute an increase in the footprint of the original structure [must] comply with all provisions of this ordinance, and in particular the dimensional requirements of Section 3.2."

After the Zoning Board granted the Special Permit and variance, the Gales filed an appeal in the Land Court under M.G.L. c. 40A, § 17 challenging the grant of the variance. After ruling that the Gales had standing to pursue the appeal, the Land Court determined that a Special Permit under M.G.L. c. 40A, § 6 is sufficient to allow reconstruction of the structure and, as a matter of law, a variance was not required.

The Appeals Court reiterated the two-part framework for evaluating extensions or alterations of pre-existing, non-conforming single- and two-family residential structures under M.G.L. c. 40A, § 6. First, the permit-granting authority identifies any ways in which the existing structure does not conform to the current zoning bylaw and determines whether the proposed alteration would "intensify the existing nonconformities or result in additional ones." If this is not the case, then the applicant is entitled to proceed with the issuance of a building permit (or a Special Permit if required by the local ordinance).

However, if the permit-granting authority determines that the alteration exceeds the scope of the existing non-conformity, a finding of no substantial detriment is also required in order for the homeowner to proceed. Importantly here, "[t]his two-part framework does not include application of a local by-law or ordinance as an additional step when proceeding to the no substantial detriment finding under the second sentence. That finding stands alone as sufficient to proceed with the proposed project…."

The SJC's ruling clarifies language in *Rockwood v. Snow Inn Corp.*, 409 Mass. 361 (1991) in which the Court seemed to strongly indicate that a municipality was, in fact, open to impose additional local requirements if there would be an intensification of the non-conformity. There, the Court declared that "even as to a single or two-family residence, structures to which the statute appears to give special protection, the zoning

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ordinance or by-law applies to reconstruction, extension, or change that would intensify the existing nonconformities or result in additional ones." *Id*. at 364 (internal quotations omitted). The Court explained that because the situation in Rockwood involved a commercial structure, this language was dicta outside the context of commercial cases.

For further information, please contact Marc J. Goldstein at mgoldstein@bdlaw.com or Brian C. Levey at blevey@bdlaw.com.

Declaratory Judgment May Be Used To Sort Out Which Decision Governs Proposed Wetland Work

While confirming that an administrative appeal to the Massachusetts Department of Environmental Protection (DEP) is the correct vehicle for addressing the local Conservation Commission's failure to issue a decision within the required 21-day period after closing the public hearing, the Massachusetts Appeals Court ruled in *Lippman v. Conservation Commission of Hopkinton*, 80 Mass. App. Ct. 1 (2011), that where ambiguity continues to exist after that appeal, an action for declaratory judgment is appropriate to resolve the dispute.

In an effort to construct a single-family house in Hopkinton, the plaintiffs filed a Notice of Intent with the Hopkinton Conservation Commission. The Commission found itself deadlocked, including failed motions to close the hearing and issue an Order of Conditions and to deny the Notice of Intent. The Chair of the Commission declared the deadlock and that no decision would be forthcoming, followed by a letter reiterating these points and stating the plaintiffs' appeal rights. The plaintiffs filed a request for a Superseding Order of Conditions with the DEP and, to confuse matters, nearly a month later the Commission issued a denial of the Notice of Intent.

The DEP issued its Superseding Order of Conditions approving the project and the plaintiffs filed a declaratory judgment action with the Superior Court seeking a declaration that the Commission's "denial" was without effect and that DEP's Superseding Order of Conditions governed the project. The Superior Court ruled that an action in the nature of certiorari under M.G.L. c. 249, § 4 (the usual method of appealing a decision by a local conservation commission) was required to address these issues, that such an action was now time-barred, and relief through a declaratory judgment was unavailable.

The Appeals Court reversed the lower court's decision that the Commission's denial would stand unless challenged in a timely certiorari action. The Appeals Court quickly concluded that the Commission's denial was untimely under the strict 21-day deadline in M.G.L. c. 131, § 40, and reiterated the Supreme Judicial Court's holding in *Oyster Creek Preservation, Inc. v. Conservation Comm. of Harwich*, 449 Mass. 859, 865 (2010) that "where a conservation commission does not issue its decision within the required twenty-one day period and the applicant appeals to the DEP, it is the DEP's superseding order that controls; any late-issued decision of the commission is without effect."

Moreover, relying on the "uncertainty and insecurity [that] exist" between the Commission's and DEP's decisions and the SJC's affirmation of the lower court's declaratory judgment in *Oyster Creek Preservation*, the Appeals Court ruled that a declaratory judgment action was the proper method for resolving this dispute.

For further information, please contact Marc J. Goldstein at mgoldstein@bdlaw.com or Brian C. Levey at blevey@bdlaw.com.

Substantial Reliance Saves Late-Recorded Variance

The Massachusetts Land Court has held that a variance is effective even if it is recorded outside the statutory one-year period so long as there has been substantial reliance on it. In *Grady v. Langone*, et al., 2011 Mass. LCR Lexis 77, the Stefanidis obtained a frontage variance in order to make possible the construction of a two-family house on their rear lot. No appeal was taken and a Certificate of No Appeal was issued by the

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Town Clerk in July, 2008. The variance provided that the applicant must record it and provide proof of recording provided to the Building Inspector prior to the issuance of a building permit. Finally, it warned, "This variance as granted is applicable for one (1) year only."

Although the Stefanidis failed to record the variance within the one-year period, they did take several steps in reliance on the variance within this time frame. They hired a general contractor, applied for and received a building permit, hired an architect to review the work progress and prepare reports, obtained a construction loan and granted a mortgage to a credit union, drew substantial funds from the loan, and began clearing the site.

An abutter wrote the Building Inspector requesting that he revoke the building permit due to the Stefanidis' failure to timely record the variance. Learning of this appeal, the Stefanidis recorded the variance on July 3, 2009, eleven (11) days after the one-year period expired. Three days later, the Building Inspector denied the revocation request citing, among other things, the Stefanidis' compliance with the conditions of the variance. On appeal, the Zoning Board of Appeals upheld this decision and the abutter appealed to Land Court.

The Zoning Act recites that "If the rights authorized by a variance are not exercised within one year of the date of grant of such variance such rights shall lapse…." M.G.L. c. 40A, § 10. Further, it states that, "No variance…shall take effect until a copy of the decision…is recorded in the registry of deeds…." M.G.L. c. 40A, § 11. In short, "a variance does not take effect until it is recorded and...the recording of a variance within one year of its grant is necessary to exercise it. *Cornell v. Bd. of Appeals of Dracut*, 453 Mass. 888, 891 (2009)." However, the Cornell Court also noted that, "We leave for another day whether the failure to record a variance may void a variance on which a variance holder substantially has relied." *Id*. at 891 & n.7. Here, the Land Court answers this question in the affirmative.

Unlike the bright line drawn by the Courts for the 20-day deadline appeals from the decisions of permit- or special-permit granting authorities under Chapter 40A, § 17, the Land Court found "no compelling policy reason for a hard and fast 'one year' rule." By statute, the variance would already have been the subject of public notice, public hearing, and an opportunity to appeal. This process is "completely unaffected by the recording or non-recording of the variance itself." Moreover, this more forgiving rule applies to other forms of zoning relief: Failure to record a special permit is not fatal where substantial use has occurred. Finally, the Land Court reasoned that the Cornell Court, while technically leaving the substantial reliance question open, intended this result by citing to case law and providing examples of substantial reliance.

The building permit was affirmed and the abutter's appeal dismissed with prejudice.

For further information, please contact Brian C. Levey at blevey@bdlaw.com or Marc J. Goldstein at mgoldstein@bdlaw.com.

Massachusetts Appeals Court Strikes Subdivision's Mandatory Open Space Conveyance to Town

The Massachusetts Appeals Court has ruled in *Collings v. Planning Bd. of Stow* that a subdivision approval condition requiring the dedication of open space for public use and actual conveyance of that open space to the town in exchange for certain waivers without just compensation violates the Subdivision Control Act. 79 Mass. App. Ct. 447, 448 (2011).

The plaintiffs, owners of a 55-acre parcel of land, sought approval of a five-lot residential subdivision. A 1,300-foot long dead-end street was to connect the project to an existing public way. Under local subdivision regulations, the length of cul-de-sac streets is limited to 500 feet, but the Planning Board, by waiver, may allow up to 1,500 feet if certain conditions are met. One such condition is that "a minimum of ten percent of

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the…of the locus…be dedicated for open space, parks or future public facilities and infrastructure."

To secure the street-length waiver, the developer proposed to transfer ownership and control of the open space to a homeowner's association and make the open space available to the public for "passive, non-motorized activities such as hiking, dog walking, cross country skiing, wildlife watching and ice-skating." The Planning Board rejected this proposal because it reserved "the right to deny access to the open space to any persons operating motorized vehicles, including ATVs, motorcycles, snowmobiles, cars, trucks, etc. and to prohibit the public, if there are multiple problems with trash, property damage, violation of restrictions, trespassing, etc."

Granting the subdivision approval, the Planning Board, in exchange for the waiver, required the plaintiffs to offer the open space first to the town's Conservation Commission, and then to a non-profit organization for open space for passive recreation with public access in perpetuity. Should both of entities decline the offer, the board required transfer of the open space to a homeowner's association, subject to a conservation restriction, with the town named as a benefitted party, and public access with appropriate restrictions.

The plaintiffs appealed to Land Court arguing that the decision violated the Subdivision Control Act. Specifically, M.G.L. c. 41, § 81Q, provides that "[n]o rule or regulation shall require, and no planning board shall impose, as a condition for the approval of a plan of a subdivision, that any of the land within said subdivision be dedicated to the public use, or conveyed, or released to the commonwealth or the county, city or town in which the subdivision is located, for use as a public way, public park or playground, or for any other public purpose, without just compensation to the owner thereof." Conceding the mandated transfer is the kind of exaction that the statute forbids, the Land Court nonetheless concluded that the condition did not violate § 81Q because "it was in exchange 'for proper and rational consideration,' i.e., the discretionary 'waiver of the street length rule.'" By driving down the project density, the Land Court believed that the open space requirement was related to the public safety concerns that underlie the maximum street length rule.

The Appeals Court disagreed finding that the Planning Board did not impose a reasonable open space requirement "but went much farther and required dedication of open space for public use, including the actual transfer of that open space to the town or a land trust." Rejecting the reasoning of the Land Court, the *Collings* Court found that "[t]he exactions…provide no additional benefit above and beyond the open space requirement that relate to the safety concerns that are the subject of the subdivision law and the street length requirements. The prohibition of § 81Q, applies 'where a planning board requires a subdivision applicant to grant land for a public purpose unrelated to adequate access and safety of the subdivision.' That is precisely what the board did here." To emphasize this point, the Court recounted that the statute's legislative history was aimed at addressing the problem of "some well-intentioned but overzealous planning boards" using "their power of approving or disapproving plans of proposed subdivisions to enforce conditions doubtless intended for the good of the public, but not relating to the design and construction of ways within subdivisions." Here, the Planning Board went too far in its zeal to control the precise language of governing the use of the open space.

This portion of the Land Court's judgment was vacated and remanded to the Planning Board.

For further information, please contact Brian C. Levey at blevey@bdlaw.com or Marc J. Goldstein at mgoldstein@bdlaw.com.

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National Developments

U.S. EPA Issues Guidance on Enforcement Discretion for the "Affiliation" Criterion of the "Bona Fide Prospective Purchaser" Defense

On September 21, 2011, U.S. EPA issued guidance to its Regional Counsel regarding the "affiliation" criterion that owners must meet in order to be considered a "bona fide prospective purchasers" (BFPP) under CERCLA. This guidance is available on EPA's website at http://cfpub.epa.gov/compliance/resources/policies/cleanup/superfund/index.cfm?action=3&sub_id=1220.

A person that qualifies as a BFPP is not considered an "owner or operator" and therefore is exempt from CERCLA liability that would ordinarily exist based on ownership of land. Several criteria must be met in order to qualify as a BFPP, including the following: (1) the release of hazardous substances must occur before the person purchased the property; (2) the person must conduct "all appropriate inquiry" before purchasing the site; and (3) the person must have "no affiliation" with any other person who has liability for the release. The following would be considered improper affiliations based on the statutory language: (a) a direct familial relationship between the purchaser and a potentially responsible party (PRP); (b) the purchasing entity is the result of a reorganization of a business entity that is a PRP; or (c) a contractual relationship between the purchaser and a PRP, except relating to the purchase of the site.

The new guidance issued by EPA discusses four issues that should first be considered in the process of determining whether an improper affiliation exists. They are: (1) whether the potential BFPP is otherwise a PRP for the site; (2) whether the potential BFPP is the same entity as the PRP or a corporate successor; (3) whether the potential BFPP is the result of reorganization of a PRP through bankruptcy or otherwise; and (4) whether the party with whom the potential BFPP may have an affiliation really is a PRP.

The guidance then addresses several relationships that should not be considered improper affiliations. First, EPA discusses two types of relationships specifically identified in the statute: contracts relating to the sale of the property to the potential BFPP, and contracts for the sale of goods or services. Second, EPA identified several additional types of relationships which generally would not be considered improper affiliations by EPA: relationships relating to other properties; relationships that arise after the purchase of the site; relationships created during title transfer; and leases between a tenant and an owner where the tenant subsequently purchases the property (assuming the tenant is not a PRP).

While the issue of "no affiliation" continues to be a confusing and difficult one, EPA's efforts to clarify this issue are interesting and helpful. We note, however, that at least one district court has rejected a party's claim for BFPP based on the "no affiliation" provision (as well as other issues). We will continue to watch this case and other BFPP developments.

For further information on avoiding CERCLA liability, please contact Jeanine Grachuk at jgrachuk@bdlaw.com.

TSCA Developments in Congress and at EPA

Legislation to amend the Toxic Substances Control Act is still in play, despite the Congressional preoccupation with other issues. EPA is making considerable progress in implementing its Enhanced Chemical Management Program under TSCA, despite roadblocks set up by the Office of Management and Budget. This report provides an update on both the legislative and administrative developments under TSCA.

To read the full report, please go to http://www.bdlaw.com/assets/attachments/BD%20Client%20Alert%20-%20TSCA%20Developments%20in%20Congress%20and%20at%20EPA%20August%2011%202011.pdf.

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California Releases Latest Versions of GHG Cap and Trade and Reporting Programs

The California Air Resources Board (CARB) has released the latest version of its greenhouse gas ("GHG") cap and trade regulation: the "California Cap on Greenhouse Gas Emissions and Market-Based Compliance Mechanism." The proposed rule brings California one step closer to implementing what will be the United States' first comprehensive emissions cap and trade program for GHGs. Under the proposed rule, registration and other administrative requirements would apply to certain stationary sources, fuel and electricity suppliers, and other affected entities next year, but the state-wide emissions cap would not take effect until 2013. The proposed text is available for a 15-day public comment period; written comments are due August 9, 2011. More information, including a copy of the redlined cap and trade rule proposal, is available here: http://www.arb.ca.gov/regact/2010/capandtrade10/capandtrade10.htm.

In conjunction with the cap and trade rulemaking, CARB also released the latest revisions and additions to its Mandatory GHG Reporting Regulation ("MRR"). According to CARB, the MRR revisions and amendments are intended to harmonize the reporting program with similar regional programs (e.g., the Western Climate Initiative) and the federal GHG reporting rule, 40 C.F.R. Part 98. The proposed revisions and amendments to the MRR are on the same 15-day review schedule as the cap and trade program, with written comments due Tuesday, August 9, 2011. A copy of the proposed MRR is available here: http://www.arb.ca.gov/regact/2010/ghg2010/ghg2010.htm.

Both the GHG cap and trade program and the MRR are key components of CARB's implementation of AB 32, the California Global Warming Solutions Act of 2006, which is aimed at reducing California's GHG emissions to 1990 levels by 2020. With a tight schedule in AB 32 for the statute's implementation and an administrative deadline for issuance of the cap and trade rule looming, the Agency plans to finalize the cap and trade rule and the corresponding changes in the MRR by October 28, 2011.

For more information on the proposed CARB regulations or on California's regulation of GHGs in general, please contact Amy M. Lincoln at (415) 262-4029, alincoln@bdlaw.com or Nico van Aelstyn at (415) 262-4008, nvanaelstyn@bdlaw.com.

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.

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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

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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.

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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).

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*

Beveridge & Diamond Named to National Law Journal's 2011 Midsize Hotlist

The National Law Journal has named Beveridge & Diamond, P.C. to its "2011 Midsize Hotlist." The list, released on July 11, recognizes twenty law firms in the 50- to 150-lawyer range around the country that have "proven they can continue to thrive in

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this troubled economy."

"We are delighted to receive recognition from the National Law Journal for not only our strong environmental practice, but also for our commitment to diversity and pro bono responsibilities" said Benjamin F. Wilson, Managing Principal at Beveridge & Diamond.

The article notes that the selected firms have, among other things, demonstrated excellence in the courtroom or boardroom; spotted a niche that eluded competitors; developed innovative management, billing or training structures; and set the standard for midsize practice.

To read the article, please see http://www.bdlaw.com/assets/attachments/BD%20Named%20to%20NLJ%20Hotlist.pdf.

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