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THE IMPORTANCE OF EVALUATING INFORMATION ACQUIRED IN LITIGATION FOR REGULATORY REPORTING PURPOSES

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Manufacturers and processors and distributors of chemical substances increasingly are the targets of litigation. Tort claims frequently involve allegations of personal injury and property damage directly caused by products containing chemical substances. Allegations in celebrated cases also have included claims for direct and indirect injuries or damage caused by inadvertent and intentional emissions from manufacturing and processing operations. When such allegations are received by manufacturers, processors and distributors of products that contain chemical substances (including pesticides), there can be legal obligations triggered that go beyond merely defending the claim. A failure on the part of a litigator to recognize these concomitant regulatory obligations can expose a client to considerable jeopardy.

The following provides some brief background on regulatory reporting obligations incumbent upon manufacturers and processors of certain categories of chemical products.

The **Toxic Substances Control Act (TSCA)**: TSCA imposes a number of regulatory obligations upon manufacturers, importers and processors of "chemical substances" and products that contain those substances. For purposes of TSCA, "chemical substances" that can be subject to the act include virtually any substances appearing in nature or as a result of manufacturing and reaction processes (but generally not pesticides, drugs, cosmetics and foods). These obligations include certain recording and recordkeeping obligations when the entity receives a report of a "significant adverse reaction" to one of its chemical substances or products containing a substance. Thus, a duty to record and keep records of such adverse reactions can be triggered by the receipt of mere *allegations* made by any person regarding a company product, process or effluent discharge and a significant adverse health or environmental reaction. There are very limited exceptions to this obligations (such as allegations made concerning adverse effects of a chemical substance previously known if the effects already are described on the label and material safety data sheet (MSDS) for the substance).

The obligations imposed by TSCA upon manufacturers and processors of chemical substances also include certain reporting obligations requiring notification to EPA. Specifically, TSCA 8(e) requires EPA to be notified immediately of "substantial risks" that are caused by exposures to or releases of a chemical substance. When acquired, such information (which can include not only new test data indicative of potential adverse effects but also can include certain allegations of adverse effects or information concerning spills or releases of chemical substances into the environment) may be reportable. EPA's interpretive policy concerning TSCA Section 8(e) establishes time limits for submitting such information to the agency and the act imposes substantial penalties for the failure to do so in a timely fashion.

The **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**. The federal pesticide law imposes similar requirements upon persons who make and distribute pesticide products. The term "pesticides" includes not only products that mitigate common pests, such as ants and roaches, but also products used to deter mammals and to destroy microorganisms, such as those used in disinfectants and some swimming pool treatment products. Thus, FIFRA Section 6(a)(2) requires pesticide product registrants to report new information to EPA concerning "unreasonable adverse effects" that might

be presented by a pesticide product or its ingredients upon human health or the environment. As with TSCA, EPA has issued interpretive policies implementing FIFRA Section 6(a)(2) and imposing time limits for the submittal of reportable information and penalties for the failure to do so. It is important for potential litigants to know that reportable information includes not only new test data concerning a pesticide product, but also can include "expert opinion" information. In certain circumstances, if a product distributor or private labeler obtains and fails to report such information to EPA, the product maker also can be held liable.

There are other statutes/and authorities administered by other federal agencies that impose analogous obligations upon the makers and distributors of other categories of products used by consumers. Thus, the makers of drugs and devices have adverse effects reporting obligations as do the makers of consumer products (such as toys). There are similar obligations in other nations and markets (such as Canada and the EU).

Product makers might acquire such reportable information through a variety of means, such as customer complaints, calls to poison control centers and through litigation. Information acquired during, or coming to light in the context of, litigation frequently includes the kinds of information that might trigger such reporting obligations. Allegations themselves can create the obligation, and the information generated during the course of litigation (*e.g.*, interviews and information generated in the course of working with retained experts), or unearthed during discovery and document and file reviews, also might be reportable to EPA. When it becomes known to EPA that a party has failed to timely report such information (and it is not unheard of for plaintiffs to want to bring such facts to EPA's attention in order to improve their position vis- -vis the product maker/defendant), EPA has shown a willingness to pursue parties who have failed to timely report such information and to impose stiff penalties. *See*, *e.g.*, EPA's December 2005 multi-million dollar settlement with DuPont for TSCA Section 8(e) violations. http://yosemite.epa.gov/opa/admpress.nsf/85daa4a9f7d7d930852570180054ef19/fdcb2f665cac66bb852570d7005d6665!OpenDocument&Highlight=0,tsca.

In today's litigation and regulatory climate, it is imperative that makers and distributors of chemical substances and products that contain such substances involve both the litigation and regulatory staffs in reviewing, evaluating and responding to information obtained in the context of litigation. The failure to do so could have enormous consequences.