MARTIN CLEARWATER & BELL LLP

DEFENSE PRACTICE UPDATE

SEPTEMBER 2016

The Unavoidability Defense in Pressure Ulcer Cases

BY: ROSALEEN T. MCCRORY, YUKO A. NAKAHARA & KAREN B. CORBETT

A common theme in actions against nursing homes involves the development or deterioration of pressure ulcers (otherwise referred to as "decubitus ulcers" or "bed sores;" all three terms are interchangeable). Although claims involving pressure ulcers can sound in medical malpractice, common law, or statutory negligence pursuant to New York's Public Health Law §2801-d, the unavoidability defense is available in all cases. Despite plaintiffs' arguments to the contrary, many pressure ulcers are neither avoidable nor preventable, facts that The National Pressure Ulcer Advisory Panel (NPUAP) and New York statutory law recognize.

10 NYCRR 415.12 defines the quality of care required in a nursing home. Pursuant to the statute, a nursing home shall ensure that:

> (1) a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable despite every reasonable effort to prevent them; and (2) a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and to prevent new sores from developing.

In order to rely on the unavoidability defense, it is essential to first understand what a pressure ulcer is. The term "pressure ulcer" denotes a skin condition or specific type of ulceration that commonly develops over bony prominences when pressure to the area disrupts blood flow. The lack of circulation can result in ischemia, cell death, and tissue necrosis.

Importantly, not all ulcers are "pressure" ulcers, even though they may be similar in appearance. If the ulcers did not form as a result of pressure, they likely have a medical cause, and may consequently have a different and/or separate medical defense. For example, a viable defense may be that they are vascular ulcers, not due to pressure. In such cases you may require the opinions of a vascular surgeon and/or an infectious disease expert to support the defense.

Pressure ulcers are classified in terms of stages. Stages I - IV are described in the Guidance to Surveyors, a publication issued by the Department of Health that outlines the regulations a nursing home must follow in order to participate in Medicare and Medicaid programs. A stage I ulcer is intact skin with non-blanchable redness of a localized area. A Stage II ulcer is a partial thickness loss of dermis which appears as a shallow open ulcer with a red/pink wound bed without slough; it may also present as an open serum filled blister. A Stage Ill ulcer is a full thickness loss of tissue, which can involve tunnelling and/or undermining. A Stage IV ulcer also presents with full thickness tissue loss, but also involves exposed bone, tendon or muscle. As Stage IV ulcers can extend into the muscle and/or supporting structures, they can sometimes lead to osteomyelitis.

Further, an ulcer is sometimes "unstageable," typically when it is covered in slough

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or eschar where the depth of the wound cannot be seen or assessed. Finally, a pressure ulcer can be classified as a Deep Tissue Injury ("DTI"), which appears as a deep purplish discoloration along intact skin, or, if on the heel, as an intact blood blister. While there may be injury to subcutaneous tissue, the extent of the injury may not be readily identifiable as it is masked by the intact skin.

Proving a pressure ulcer is unavoidable will involve examining the nursing home resident's complete medical picture. Residents usually present with clinical conditions which increase the risk of developing pressure ulcers. These co-morbidities often include immobility, obesity, urinary/bowel incontinence, diabetes, thyroid disease, cancer, end stage renal or heart disease, peripheral vascular disease, malnourishment, and dehydration. Cognitive loss is also an important co-morbidity to consider since dementia has been linked to an increased risk of pressure ulcers. Patients with dementia often fail to recall whether and when they changed positions.

Pursuant to New York Public Health Law §2801-d, the defense that the facility exercised all reasonably necessary care to prevent and limit the injury alleged must be affirmatively pled. The statutory unavoidability defense requires a showing that "all care reasonably necessary" was taken to prevent the pressure ulcer from forming and that the resident was given the necessary treatment and services to promote healing, prevent infection, and to prevent new sores from forming.[1]

Specifically, the defense must demonstrate that the resident developed a pressure ulcer despite 1) a proper assessment of the resident's risk level for pressure sores; 2) the formulation of an appropriate care plan based on the resident's risk level that incorporated interventions aimed at pressure ulcer prevention and/or healing; and 3) documentation that the staff properly implemented the care plan.

Proper assessment of a resident's risk level for pressure ulcers requires a complete nursing assessment. All residents admitted to a nursing home must be evaluated for their risk of skin breakdown utilizing the Braden Scale. The Braden Scale assesses a person's risk for pressure ulcers by evaluating six criteria: sensory perception, moisture, activity, mobility, nutrition, and friction and shear. The scoring determines the resident's risk level for pressure ulcers and is the basis for determining what prevention protocols and/or treatment is necessary.

Importantly, Medicare guidelines provide that nursing home residents must also be reassessed periodically and when they have a "significant change in status."[2] Per the guidelines, the development of a new pressure ulcer that is Stage II or higher, or a deterioration of an existing pressure ulcer, is considered to be a significant change in status that triggers a reassessment of the resident, and an update to the care plan.

Following the nursing assessment, or reassessment, a care plan must be developed outlining the interventions to be implemented for that individual. The interventions should address the individual's needs based upon the diagnoses identified during the nursing assessments. Proper and thorough documentation is crucial to the success of the unavoidability defense. The records must demonstrate that the care plan was properly implemented, and should include information regarding turning and positioning, toileting, and wound/ulcer evaluations. The wound evaluations should describe in detail how the wound is progressing.

Thus, a close examination of CNA accountability records is a critical part of all pressure ulcer cases and care should be taken to ensure compliance with the care plan. Clearly, cases involving claims related to the development or progression of pressure ulcers can be thoroughly defended based on the unavoidable defense. Support from the record that the resident's risk level for pressure ulcers was properly assessed and that a proper care plan was developed and implemented will support a defense that the facility exercised all care reasonably necessary to prevent and limit the development or progression of pressure ulcers.

1. NY Pub Health L § 2801-d (2014)

2. *Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual Version 1.14*, Centers for Medicare & Medicaid Services (October 2016), at 2-19, available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.

3. *Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual Version 1.14*, Centers for Medicare & Medicaid Services (October 2016), at 2-25, available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.

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Prepare Your Facility For Deaf Residents And Guests

By Gregory B. Reilly and Adam G. Guttell

In operating a nursing home or hospital, it is natural to take for granted the intent to care and accommodate residents who, after all, have come to your facility because of their special needs. Sometimes overlooked, however, are the requirements to provide effective communication for deaf residents and guests.

Federal, state, and local laws not only prohibit discrimination based on protected categories, these same laws provide for equal access to health care facilities, including nursing homes, which presents an issue when patients, residents, or guests are unable to communicate or receive critical information during the course of treatment.

Title III of the Americans with Disabilities Act ("ADA") covers "public accommodations." In the healthcare industry, that includes hospitals, nursing homes, and professional medical offices. In fact, nursing homes are specifically covered under Title III as "social service establishments."

In addition to the ADA, Section 504 of the Federal Rehabilitation Act ("Rehabilitation Act"), requires that "no otherwise qualified individual with a disability in the United States…shall, solely by reason of his or her disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal Financial Assistance."[1] In this context, nursing homes which receive federal financial assistance, such as Medicare or Medicaid, are required to comply with Section 504.

To ensure compliance, facilities must take certain measures to guarantee effective communication. To do so for deaf residents, patients, and guests, facilities must provide "auxiliary aides," which are devices or methods for ensuring adequate communication. The ADA regulations, which work hand-in-hand with the Rehabilitation Act, require an individualized assessment of each person with a *communication related disability* to identify the correct type of auxiliary aid. Auxiliary aides may be appropriate and compliant so long as they function properly and have been procured as a result of a true individualized assessment of the patient, resident, or guest. Under Title III, examples of auxiliary aids include, but are not limited to, qualified interpreters, computer-aided transcriptions services, assistive listening devices, and open and closed captioning. While there are various auxiliary aids, the important criteria is whether the aid provides effective communication for the patient.

Compliance is important, as hospitals and other covered facilities, anecdotally, have seen an uptick in claims related to failure to provide equal access to hearing impaired individuals. Equal access, in this context, means effective communication. The Health and Human Service's ("HHS") Office for Civil Rights (OCR) has determined that effective communication must be provided at "critical points" during care:

> These would include those points during which critical medical information is communicated, such as at admission, when explaining medical procedures, when an informed consent is required for treatment and at discharge.[2]

In the context of a nursing home, although not widely tested, this likely refers to only the critical points in care. Day-to-day functions likely do not qualify. However, best practices include providing residents with operational auxiliary aides throughout their day. Importantly, use of handwritten notes do not constitute valid auxiliary aides for "critical points."

Further, facilities must be aware of guests or companions who are hard of hearing and involved in a resident's care. The ADA requires that auxiliary aides be furnished to "individuals with disabilities" and "companions who are individuals with disabilities."[3] Companions are defined as "a family member, friend, or associate of an individual seeking access to, or participating in, the goods, services, facilities, privileges, and advantages, or accommodations of a public accommodation."[4]

The trend in lawsuits involving claims of ineffective communication has been to challenge the effectiveness of the auxiliary aides provided. Plaintiffs frequently claim that the only effective communication is by means of a qualified live interpreter, which tends to be the most costly option. However, it also is the most conservative approach to stave off litigation. Claimants filing suit under the ADA and the Rehabilitation Act

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1.Qualified individuals are:
1) Individuals who have a physical or mental impairment that substantially limits one or more major life activities;
2) Individuals who have a record of a physical or mental impairment that substantially limited one or more of the individual's major life activities; and
3) Individuals who are regarded as having such an impairment, whether they have the impairment or not.

2. U.S. Department of Health and Human Services, Office for Civil Rights, Region III, Letter of Findings, Ref. No. 03913037 (December 12, 1991), at 5
3. 28 C.F.R. § 36.303(c).
4. 28 C.F.R. § 36.303(c)(i)(ii).

Limiting Litigation Risk in the

By: Daniel A. Freidlin and Michelle A. Frankel

The treatment of obese patients may give rise to unique issues in medical decision making and may carry additional legal responsibilities. The management of these patients may be complicated by diagnostic challenges in certain conditions, as well as additional surgical and medical comorbidities. This is significant because it is estimated that more than one-third of the American population is considered to be obese.[1] Obese patients are more likely to develop type II diabetes, cardiovascular disease, sleep apnea, and stroke. The obese patient may also be an increased surgical risk. As all patients should be informed and educated about their individual and medical and surgical risks, it is important that this discussion include complications associated with the comorbidities of obesity.[2]

When medical complications occur, litigation often follows. The increased incidence of obesity in the population has led to an increased number of personal injury lawsuits involving obese patients. Well-documented records are often helpful in defending negligence lawsuits when they arise. Thus, medical providers should ensure that conversations about weight education and guidance, including interventions proposed and whether such recommendations were followed, are well documented.

Informed refusal forms have been utilized by some to limit liability risk by "…informing patients about how obesity impacts their overall health and/or a specific health issue and having patients sign a document stating that they were advised but chose not to follow recommendations."[3] These forms may reduce damages owed by the defendant as some courts have

1. Overweight & Obesity: Adult Obesity Facts, Centers for Disease Control and Prevention, (September 21, 2015), https://www.cdc.gov/obesity/data/adult.html.

2. Medical providers may inform their patients that individualized weight management strategies, self-examination, and having realistic weight loss goals, may be beneficial as even modest weight loss of five to ten percent total body weight can lead to significant reduction in the risk of type II diabetes and hypertension (Leigh McKinney, Neil Skolnik, M.D. and Adam Chrusch, Diagnosis and Management of Obesity, American Academy of Family Physicians(2013), available at http://www.aafp.org/dam/AAFP/documents/patient_care/fitness/obesity-diagnosis-management.pdf) . Overall, simultaneous care coordination among primary care providers, dieticians, physical therapists, specialists, and community resources can further promote long-term obesity treatment and management. Id.

3. Alicia Gallegos, Obesity Malpractice Claims Up 64%, Study Shows, Clinical Endocrinology News (July 10, 2014), http://www.clinicalendocrinologynews.com/home/article/obesity-malpractice-claims-up-64-study-shows/07aa8681c289b615a064f4d89e232771.html?tx_ttnews[sViewPointer]=1.treatment and management.

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seek monetary damages, attorneys' fees, and injunctive relief.

It is not enough, however, to have the phone number for a live interpreter. Facilities must have in place the means to efficiently and swiftly access auxiliary aides to avoid any claims of ineffective communication. To do so, facilities must (1) set up a relationship with a qualified interpreter agency or auxiliary aid provider; (2) prepare and implement proper procedures and policies related to equal access for hearing impaired individuals (including what to do when the auxiliary aid is unavailable or malfunctioning), and (3) conduct thorough and regular training for all staff who may come in contact with patients.

Further, policies and procedures should account for individualized assessments of individuals requiring auxiliary aides and designation of appropriate staff to conduct such assessments. Frequently, claims result from well-meaning, but untrained staff unaware of the procedures for engaging a live interpreter or similar auxiliary aid. For example, if the facility choses to use Video Remote Interpreting ("VRI"), it must ensure that this equipment remains in good working order. Frequently, VRI's are challenged as ineffective due to complaints of poor image quality, poor internet connections, small screens, and untrained staff taking too long to hook-up the machine. Facilities can avoid these complaints through effective and frequent training. A good practice is to integrate effective communication and auxiliary aide training into regular staff in-service.

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Treatment of Obese Patients

held patients accountable for contributory negligence due to their failure to follow this medical advice.[4]

At least one study has shown an increasing number of malpractice cases citing failures by physicians to monitor, treat, or educate patients regarding the risks of their obesity.[5] Internal medicine, family practice and geriatric medicine specialists have the opportunity to recognize, educate and prevent obesity at its onset, so they are not only in a key position to address this growing population but are also often the target of the above-referenced lawsuits. Unfortunately, overweight and mildly obese patients often do not receive timely advice on weight management despite having the greatest chance of obtaining a healthy weight.

Providers can enhance their treatment, while limiting their legal exposure, by ensuring that weight is measured, and trends in body mass index are discussed with the patient during all office visits. Ensuring that patients understand the significance of measurements, such as blood pressure, glucose, and cholesterol levels, can foster discussions about weight loss by explaining and emphasizing how excess weight impacts the body. Such discussions may also decrease the probability that a patient develops a medical complication that may lead to a malpractice lawsuit. A well-documented medical record, including notations of the patient's weight at each visit and that the patient was counseled regarding the importance of weight loss, may be helpful if litigation ensues.

Hospitals and long-term care facilities are also targeted by plaintiff's attorneys claiming that equipment utilized, such as examination tables or wheelchairs, were incapable of supporting heavier patients. Lawsuits have also been initiated claiming that nursing staff were not properly trained on the use of equipment, such as Hoyer lifts, resulting in injury to the patient. Obese patients may also be at a greater risk for "slip and falls" or tripping. Moreover, obesity places residents of long-term care facilities at a greater risk of developing pressure ulcers due to, among other things, limited mobility. As the incidence of obesity in the population increases, facilities should ensure that they are appropriately staffed, trained, and equipped to manage the needs of these patients.

Surgeons and anesthesiologists may also be named in lawsuits involving the morbidly obese, as this patient population is at an increased risk for intraoperative and postoperative complications, i.e. increased risk of infection, wound healing issues, and pulmonary embolism. Proper education and counseling prior to surgery, and documentation of a proper informed consent will assist in defending a case when a lack of informed consent is claimed.

Obese patients may also be at a greater risk for "slip and falls" or tripping.

Importantly, the risk associated with bariatric surgery patients does not stop with the surgeon. In one recent case successfully defended by Martin Clearwater & Bell LLP, the plaintiff claimed that our client paramedic delayed transport of the patient. The attorney for the plaintiff believed that the ambulance was not equipped with a transport chair sufficient to support the weight of the patient. It was alleged that this unnecessarily delayed treatment for a pulmonary embolism. However, we were able to demonstrate through our experts, fact witnesses, and documentation that the equipment utilized by our clients was not only capable of supporting the patient's weight, but also that it was the patient's family that delayed treatment as they were insistent upon transport to a different facility. In that case, a well-documented Pre-Hospital Care Report was instrumental to our obtainment of a dismissal of the plaintiff's claims.

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4 Timothy Caulfield, LLM, Obesity, Legal Duties, and the Family Physician, Canadian Family Physician, 1129-1130 (2007), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1949277/pdf/0531129.pdf. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1949277/.

5 See, The Doctors Company "An Overview of Obesity-Related Claims" available at http://www.thedoctors.com/KnowledgeCenter/PatientSafety/articles/CON_ID_000281.

MCB Spotlight:
Nursing Home Practice Group

Claims against nursing homes and long-term care facilities continue to rise and indemnity payments involving these facilities have increased dramatically over the last several years.

MCB has been successfully defending nursing home litigation claims for decades. In response to the recent trends in nursing home litigation, we have expanded our team of attorneys dedicated to the defense of these cases and compiled an extensive database of medical and legal research, in addition to medical and nursing experts in this area. Our Nursing Home Defense Practice Group has experience defending claims involving:

- Prevention and treatment of pressure ulcers;
- Resident falls;
- Alleged neglect and abuse;
- Alleged assaults upon residents;
- Nutrition and hydration issues;
- Medication errors, and
- Risk management advice.

Standing left to right: Thomas A. Mobilia, John J. Barbera, Yuko A. Nakahara, Charles S. Schechter, William P. Brady, Scott O. Frycek, Karen B. Corbett

Seated left to right: Jeffrey A. Shor, Rosaleen T. McCrory, Kenneth R. Larywon

By participating in the development of case law in this area, along with our extensive experience in defending traditional medical malpractice claims for over 100 years, MCB is able to provide its clients with risk management counseling and an aggressive defense of claims.

MCB is actively involved in alternative dispute resolution, including mediation of nursing home cases where appropriate. For more information on the Nursing Home Practice Group, contact Rosaleen T. McCrory at mccror@mcblaw.com or (516) 222-8505.

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Recent Defense Verdicts

August 2016: Senior Trial Partner, John J. Barbera, assisted by Associates Aisling McAllister and Olivia DeBellis, obtained a defense verdict in Supreme Court, Bronx County before Judge Julia Rodriguez. The case involved the defense of a commercial building in Manhattan on a claim of failure to inspect and maintain safe premises. The plaintiff alleged that he was confined to a wheelchair and permanently disabled after being struck in the head by a metal paper towel and trash receptacle that was built into a wall. The plaintiff underwent cervical fusion of his fifth cervical vertebrae as a result of the injury and claimed onset of chronic regional pain syndrome. Plaintiff sought over six million dollars in damages. The defense called an expert in materials science and bio-mechanical engineering to challenge the plaintiff's theory of how the accident occurred. The defense also disputed the relationship of plaintiff's claimed injuries to the accident. The jury returned a defense verdict based largely on the expert testimony of the bio-mechanical engineer who demonstrated that the unit could not have fallen down given the reasonably safe and sound manner in which it was securely fastened to the wall.

June 2016: Senior Trial Partner Jeffrey A. Shor obtained a defense verdict in a dental malpractice case. During the course of performing an oral evaluation of a four-year old, our client made an incidental finding of either a fractured tooth or an extra tooth. Regardless of the diagnosis, the dentist decided it was necessary to remove the fragment of tooth and proceeded to do so. The plaintiff claimed that during the course of the removal of the fragment, the dentist caused a nerve exposure which led to a severe infection, a four day hospitalization, and the extraction of the tooth. The defense argued that approximately one week after the dentist removed the fragment of tooth, the infant was hit in the same area of her face as the removal of the fragment with a soccer ball. The defense further argued that it was the trauma from the soccer ball which caused the severe infection. The defense also argued that had the defendant caused a nerve root exposure, the infant would have demonstrated severe and obvious clinical symptoms of a nerve root exposure, including severe pain and discomfort, which never occurred. The jury deliberated for less than thirty minutes and returned a verdict in favor of the defendant, pediatric dentist.

May 2016: Senior Trial Partner Michael A. Sonkin, assisted by associates Samantha Shaw and Katherine Baxter, obtained a defense verdict in the Supreme Court Kings County following a three-week trial. The case was tried before Justice Gloria Dabiri and involved a 37-year old woman who delivered twins via Cesarean section and then was found to have uterine atony and heavy bleeding that was unresponsive to medical treatment. A life-saving hysterectomy was performed after the patient appeared to develop a coagulopathy. During the hysterectomy, an inadvertent transection of the left ureter occurred that was not known to the physicians. A cystoscopy was performed in the operating room and showed dye in the bladder but without visualizing the ureteral jets. This demonstrated that at least one, and potentially both ureters, was functioning, although it did not rule out the possibility of injury to one of the ureters. Following this inconclusive study, the decision was made to transfer the patient to recovery without seeking a urology consultation due to her extreme blood loss (9 liters) and the risk for further complications by prolonging the surgery. Post-operative elevation in her creatinine was recognized promptly and a transected ureter four centimeters proximal to the bladder was identified. A nephrostomy tube with drainage bag was placed, and the patient ultimately underwent a repair two months later. Plaintiff argued that a urologist should have been called to the operating room once the difficulty of the surgery was recognized and certainly once the cystoscopy was inconclusive, and that a urologist would have identified the injury and repaired it in the operating room to avoid the need for the nephrostomy tube and drainage bag. The defense successfully argued that the post-partum hemorrhage was life threatening, that the primary focus was appropriately on controlling her bleeding, and that further exploration and cutting of tissue necessary to identify and repair the ureter would have posed unacceptable risks to the patient. Following the lengthy trial, the jury deliberated for approximately twenty minutes before delivering a unanimous defense verdict.

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MCB NEWS

MCB OPENS CONNECTICUT OFFICE

Martin Clearwater & Bell LLP has expanded its presence to Stamford, Connecticut to better serve the needs of our clients.

We are located at 1 Landmark Square in Stamford, CT.
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MCB has a team of attorneys admitted to practice in Connecticut and who are experienced in defending medical malpractice, general liability, and employment and labor cases in Connecticut courts. For more information on MCB's Connecticut practice, contact Bill Brady at bradyw@mcblaw.com or John Barbera at barbej@mcblaw.com.

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May 2016: Senior Trial Partner Nancy J. Block, assisted by Partner Jessica A. Bresnan and Associate Samantha E. Shaw, obtained a defense verdict in Kings County. The matter involved a 30 year old woman who claimed that our clients, an endocrinologist and a neurologist, failed to diagnose pulmonary arterial hypertension. She alleged that had she been diagnosed at an earlier stage, she would not have needed 24-hour continuous IV Flolan – a medication which caused her to become debilitated and unable to pursue her career as a lawyer. The defense argued that plaintiff had been previously diagnosed by another neurologist with a partial complex seizure disorder that was consistent with her symptoms, and she underwent two prior negative cardiac evaluations. Our clients were entitled to rely on this diagnosis and the negative work-ups. There was also no indication to refer her to a cardiologist for additional studies. The defense explained the medicine associated with pulmonary arterial hypertension and why it was not diagnosable when plaintiff treated with our clients. Further, the defense demonstrated that plaintiff would never have been successfully treated with oral calcium channel blockers, and the continuous IV Flolan is the reason that she has survived with a devastating disease. The jury returned a verdict in favor of all defendants.

Defense Practice Update is published by Martin Clearwater & Bell LLP. This newsletter is intended to provide general information about significant legal developments only, and should not be used for specific action without obtaining legal advice. Anyone wishing to retain Martin Clearwater & Bell LLP should contact Michael A. Sonkin, Managing Partner, 220 East 42nd Street, New York, New York 10017, (212) 697-3122.

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