

Federal Regulators Looking to Improve Testing of Generic Medications: Issues regarding safety concerns over generic medications produced overseas were raised at a recent briefing in Washington. Specifically, some generic heart medications produced by companies based in India do not work in the same way as their brand-name counterpart. Preston Mason, a researcher at Brigham & Women's Hospital, authored a study published last year in the *Journal of Clinical Lipidology* that looked at 36 generic versions of the cholesterol drug Lipitor produced in 15 other countries and found impurities in many of them. Mason found that the impurity found had the possibility to "compromise" effective management for the treatment of hypercholesterolemia. To combat this, the U.S. Food and Drug Administration launched a \$20 million testing program last September to address these growing concerns, which account for nearly 80% of the country's prescriptions. For more information, go to <http://ow.ly/uFzmQ>.

Physician Owned Distributorships under Justice Department Scrutiny: The Justice Department has filed a False Claims Act enforcement action, the first of its kind, against a California physician alleging, in pertinent part, that the financial incentives received by the physician as a return on investment in a Physician Owned Distributorship were improper. A Physician Owned Distributorship (a "POD") is a medical device company that generally has surgeons or physicians as owners or investors. Typically, a physician investor will purchase shares in the company and, thereafter, receive payments of dividends from the company on a regular basis as a return on investment. The potential conflict of interest, which is now being investigated for the first time, comes into play when the physician investor also uses the products purchased from the POD (either directly by the physician or indirectly by the hospital where the physician performs his or her surgeries) in his or her practice. The physician currently under investigation would regularly use medical devices purchased from the POD in which he was an investor and, it is alleged, his use of these products increased after he made his initial investment.

NY Appellate Division Holds Prompt Pay Law is enforceable through a private right of action: In *Maimonides Med. Ctr. v. United Am. Life Ins. Co.*, decided March 5, 2014, Maimonides brought action against the insurer alleging numerous causes of action, including violation of the Prompt Pay Law, based on the insurer's payment of merely \$4 million for \$19 million of total services rendered. Maimonides alleged that the insurer never provided any written notice as required under the law for the underpayment, and that the insurer was responsible to pay in full the amounts that Maimonides billed plus interest. The insurer argued that the Prompt Pay Law does not create a private right to sue, and that the law is only enforceable by administrative action of the Department of Financial Services, such as through the issuance of fines for violations. Maimonides contended that the law implies a private right of action. The Appellate Court agreed with Maimonides, and held that the Prompt Pay Law implies a private right of action. The appellate court held that the statute was enacted to protect health care providers and patients from late payment of claims, and the relief afforded under the statute would not adequately protect health care providers and patients unless they could sue to enforce these rights.

Kern Augustine Conroy & Schoppmann, P.C. appointed General Counsel of the New York State Osteopathic Medical Society (NYSOMS): Kern Augustine Conroy & Schoppmann is pleased to announce that it has been retained as General Counsel for NYSOMS.

For more information on the above items, contact Kern Augustine Conroy & Schoppmann, P.C. at 1-800-445-0954 or via email at info@DrLaw.com.



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