DORNBUSH SCHAEFFER STRONGIN & VENAGLIA, LLP

WINTER 2012

NEWSLETTER

To our clients and colleagues:

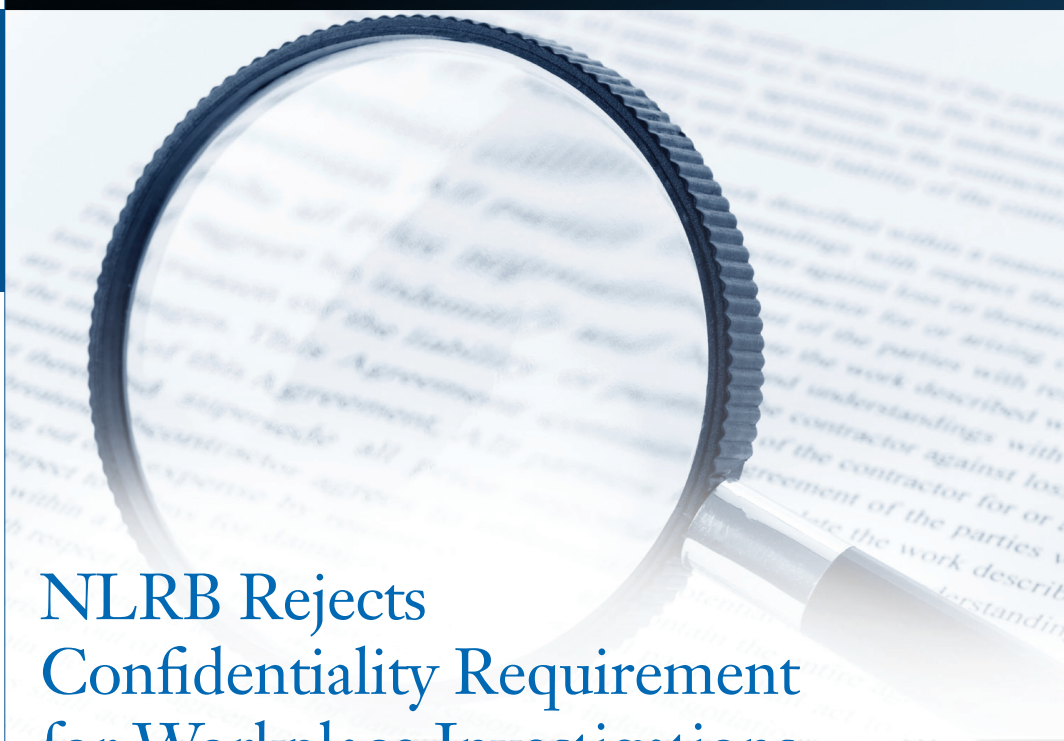
Welcome to DSSV's Winter 2012 Newsletter. This issue features articles on employment law developments that should be of interest to all of our clients as well as certain marketing practices of special interest to our clients in the pharmaceutical industry.

Employment law has seen recent developments in the areas of confidentiality requirements in workplace investigations and in employers recouping overpayments. During the summer, the National Labor Relations Board (NLRB) ruled that a blanket policy or rule prohibiting employees from discussing ongoing internal investigations of employee misconduct violates an employee's statutory right to engage in concerted activity. Further, as of November 6, 2012, the New York Labor Law provides that an employer is permitted to recapture overpayments of wages that resulted from a mathematical or other clerical error. These topics are covered in two articles co-authored by my partner Cody Fitzsimmons and our associate, Shira Forman.

My partner Bruce Handler authored an article on recent government responses to the problems in the pharmaceutical industry created by commercial activities outside established distribution channels. Specifically, this article discusses the impact of the "Gray Market" on shortages in prescription drugs, and the continuing struggle to combat fraudulent internet pharmacies and the proliferation of counterfeit, adulterated and otherwise defective prescription drugs.

DSSV wishes you a happy holiday season and prosperous New Year. We look forward to a successful 2013.

Landey Strongin
Partner



NLRB Rejects Confidentiality Requirement for Workplace Investigations

Cody Fitzsimmons

Shira Forman

A blanket policy or rule prohibiting employees from discussing ongoing internal investigations of employee misconduct violates employees' statutory right to engage in concerted activity, according to a recent decision of the National Labor Relations Board (NLRB).

In *Banner Health Systems v. Navarro* (July 30, 2012), the NLRB ruled that an employer's policy or rule prohibiting employees from discussing ongoing internal investigations violated Section 7 of the National Labor Relations Act (NLRA). Under Section 7, both union and non-union employees are guaranteed the right "to engage in [ ] concerted activities for the purpose of collective bargaining or other mutual aid or protection."

Banner Health involved a hospital employee who complained that he was retaliated against by his supervisors after raising concerns about the hospital's procedures for cleaning surgical instruments. At the outset of the hospital's internal investigation, the hospital's human resources consultant advised the employee not to

continued on page 2

DSSV Launches New Website

DSSV is happy to announce the launch of our new website. Please visit our new site at www.dssvlaw.com.

NLRB Rejects Confidentiality Requirement for Workplace Investigations

continued from page 1

discuss the matter with his coworkers while the investigation was ongoing. This warning was routinely given to employees by the hospital.

The NLRB ruled that maintaining and applying a rule prohibiting employees from discussing ongoing investigations of employee misconduct was a violation of the NLRA. It concluded that, in order to justify a prohibition on employee discussion of an investigation, the employer must show that it has a "legitimate business justification that outweighs employees' Section 7 rights." A generalized concern for maintaining the integrity of an investigation is insufficient; instead, an employer must determine in each instance whether confidentiality is warranted for a particular purpose. Examples of concerns that might justify a confidentiality instruction, according to the decision, are: the need to protect witnesses; the need to prevent evidence from being destroyed; the need to protect testimony from being fabricated; and the need to prevent a cover-up.

The NLRB's decision limits but does not eliminate an employer's ability to require employees to refrain from discussing ongoing internal investigations. Pursuant to the Board's decision, employers must determine on a case-by-case basis whether confidentiality may be required.

Cody Fitzsimmons

Shira Forman

Change in New York Labor Law Allows Employers to Recoup Overpayments

A recent amendment to New York's Labor Law has broadened the categories of deductions that an employer may make from an employee's wages. Of particular significance is a new provision that permits employers to recapture overpayments of wages that resulted from a mathematical or other clerical error by the employer. The amendment went into effect on November 6, 2012, and, unless extended, will expire and be deemed repealed three years after the effective date.

The position of the New York Department of Labor, as expressed in a series of opinion letters, had been that the recoupment of overpayments through wage deductions constituted a violation of Labor Law §193, which sets out categories of deductions that employers may make from employees' wages and the circumstances under which the deductions may be made. The opinion letters also made clear that employers were prohibited from requiring employees to return overpayments through payment by separate transaction. These prohibitions left employers with only two means of recouping overpayments. They could either request that the employee separately repay the overpayment, making clear that failing or refusing to do so would not result in any form of adverse employment action, or seek relief in a proceeding against the employee, *i.e.* an action in court.

The amendment to Labor Law §193 specifically permits recovery of an overpayment of wages where such overpayment is due to a mathematical or other clerical error by the employer. In recovering such overpayments, the employer must comply with regulations which will be promulgated by the Commissioner of the Department of Labor and will include, but not be limited to, provisions governing: the size of the overpayments covered by §193; the timing, frequency, duration and method of recovery; limitations on the periodic amount of such recovery; a requirement that notice be provided to the employee prior to the commencement of such recovery; a requirement that the employer implement a procedure for disputing the amount of such overpayment or seeking to delay commencement of such recovery; the terms and content of such a procedure; and a requirement that notice of the procedure for disputing the overpayment or seeking to delay commencement of such recovery be provided to the employee prior to the commencement of such recovery.

As of this writing, the Commissioner of Labor has not yet issued the regulations. Given that the amendment states that in recovering overpayments, employers "shall" comply with regulations promulgated by the Commissioner for that purpose, employers are advised to wait until such regulations are promulgated before making deductions from wages for overpayments.

Pharmaceutical Law: Recent Government Responses to the Gray Market and Rogue Internet Pharmacies

Bruce Handler

There has been a notable increase in recent years in the sale of prescription drugs outside of contractually authorized and regulated distribution channels, due largely to the globalization of the economy, the expansion of the gray market and the proliferation of rogue internet pharmacies. While much of this distribution activity is not necessarily prohibited by state or federal law, it nevertheless presents grave risks both to the public welfare and to the proprietary, legal and reputational interests of drug manufacturers: shortages of life-sustaining drugs; price gouging; and the sale of counterfeit, expired and adulterated drugs. In recent months, Congress, the Justice Department and the Food and Drug Administration, as well as the international police organization Interpol, have taken steps aimed at reining in these unauthorized activities.

The scope and effectiveness of these government responses to the harms caused by unauthorized commerce in pharmaceutical products is very much an open question. Under many circumstances, it will be left to drug manufacturers and other legitimate actors in the pharmaceutical industry to enforce their rights and protect their interests through private measures, including litigation.

CONGRESS ISSUES REPORT ON DRUG SHORTAGES AND THE GRAY MARKET DISTRIBUTION OF PRESCRIPTION DRUGS

On July 25, 2012, Congress released a joint staff report examining how gray market actors have exploited the shortages of certain drugs by selling those drugs to hospitals and other health care providers at vastly inflated prices. The Report, entitled "Shining Light On The 'Gray Market': An Examination Of Why Hospitals Are Forced To Pay Exorbitant Prices For Prescription Drugs Facing

Critical Shortages", found that the market for certain prescription drugs – particularly injectable drugs used to treat patients with cancer and other serious diseases – has experienced critical shortages in recent years. (An October 2011 FDA Report, "A Review of FDA's Approach to Medical Product Shortages", found that the number of drug shortages annually tripled from 2005 to 2011, with sterile injectables accounting for 80% of those shortages.) The Report concluded that, in approximately two-thirds of the drug distribution chains studied, prescription drugs leaked into the gray market through pharmacies which, rather than dispensing drugs to their customers, resold the drugs to gray market wholesalers. As drugs passed through gray market distribution chains, they were significantly marked up in price. Ultimately, hospitals and other healthcare providers, unable to obtain those drugs through regular channels, were left with little choice but to purchase drugs at exorbitant prices, sometimes as high as 3,000 % to 4,000 % over typical contract prices.

While the gray market was seen to exacerbate and exploit drug shortages by withholding products from end customers, it is not considered the primary cause for these shortages. The Report found that the most common cause for drug shortages, particularly with respect to generic injectables, was a manufacturer's decision to shut down a facility to address drug quality problems.

Legislative responses to this problem remain a work in progress. The Food and Drug Administration Safety and Innovation Act, which was signed by President Obama on July 9, 2012, contains certain provisions designed to alleviate the drug shortage problem. While this statute does not address the role of the gray market, it does require a manufacturer to provide early notification to the FDA when it plans to discontinue or interrupt the manufacture of life-supporting or life-sustaining drugs or drugs intended for use in the treatment of a debilitating disease, where the discontinuance or interruption could lead to a shortage of that drug in the U.S. The statute would also require the Secretary of the Department of Health and Human Services to maintain a drug shortage list, including the name of the drug in shortage, the manufacturer, the reason for the shortage and the estimated time frame of the shortage.

CRIMINAL PROSECUTION FOR ILLEGAL DIVERSION OF PRESCRIPTION DRUGS

Although gray market activity does not by definition violate state or federal laws, criminal authorities may prosecute businesses that engage in criminal conduct as part of a product diversion scheme. It does not appear, however, that such cases are pursued aggressively or in great numbers and those that are pursued tend to involve egregious conduct. In August of this year, Altec Medical, Inc., a South Carolina medical supplier, pleaded guilty to one count of conspiracy to defraud the FDA as part of a scheme to divert prescription drugs.

continued on page 4

Pharmaceutical Law:
Recent Government Responses to the Gray Market and Rogue Internet Pharmacies

continued from page 3

The government charged that Altec paid its supplier and co-conspirator William D. Rodriguez approximately $55 million for prescription drugs that Rodriguez had purchased illegally from individuals not properly licensed to sell such products. The government also alleged that Altec and Rodriguez attempted to conceal the scheme by falsifying business records, including FDA-required "drug pedigrees". At his sentencing, Rodriguez admitted that the drugs were often obtained in street level transactions where people sold their medication for money, and from cargo thefts. The United States District Court in Miami ordered Altec to pay a $2 million fine and to forfeit $1 million. In September 2012, Rodriguez was sentenced to 10 years in prison for his role in the scheme.

FDA LAUNCHES CAMPAIGN AGAINST FRAUDULENT ONLINE PHARMACIES

The sale of counterfeit and adulterated prescription drugs, whether by fraudulent internet pharmacies or other unregulated sellers, remains a grave threat to the public. Congress thus far has failed to pass online anti-piracy legislation that would provide tools to restrict the activities of many internet pharmacies. Congress also failed to take a significant step toward containing these problems when a provision establishing a federal drug "trace and track" system – which would monitor drugs throughout the supply chain and help to identify consumers at risk – was dropped from the final version of the Food and Drug Administration Safety and Innovation Act, signed by President

Obama in July. That legislation does, however, include certain measures aimed at internet pharmacies and counterfeit and adulterated drugs, including: (1) providing the FDA with extraterritorial jurisdiction over any violation of the Food, Drug and Cosmetic Act relating to any article intended for import to the U.S., and (2) enhancing the penalties for those who knowingly and intentionally adulterate a drug or commit certain prohibited acts related to the forging and counterfeiting of drugs.

On September 28, 2012, the FDA launched a national campaign to raise public awareness about the prevalence of fraudulent internet pharmacies, emphasizing the danger to public health of these "rogue internet pharmacies". The campaign, entitled "BeSafeRx – Know Your Online Pharmacy", provides educational resources for patients and caregivers to educate them about particular online suppliers and to verify that the medication they purchase is in fact what their doctors have prescribed.

The new FDA campaign was prompted by concerns for public safety – specifically, the substantial risk that drugs purchased from online pharmacies will be counterfeit, contaminated, expired, contain no active ingredient or the wrong amount of active ingredient. The BeSafeRx campaign follows certain high profile instances of counterfeit drugs reaching American patients. Earlier in 2012, the FDA warned certain doctors and cancer patients that they had purchased fake Avastin, an expensive injectable cancer medicine, from Canada Drugs, a gray market wholesaler. In May 2012, the FDA issued a warning after learning that online customers had bought fake versions of generic Adderall, a medication for the treatment of attention deficit disorder.

In September and October 2012, the FDA took action to close down approximately 4,100 illegal pharmacy websites, including more than 3,700 web addresses owned by Canada Drugs. The FDA action included letters of warning to managers of recognized websites and notices to registries, internet service providers and domain name registries notifying them that the products for sale on their sites violated U.S. law.

The FDA took these actions as part of a broad international campaign coordinated by Interpol, named "Operation Pangea V" ("V" because it is in its fifth year), to combat the online sale of counterfeit prescription medicines. The operation brings together the resources of customs agencies, health regulators, national police and the private sector from nations throughout the world. Operation Pangea V took place from September 25, 2012 through October 2, 2012. In the course of targeting illegal pharmacies worldwide, 3.7 million doses of fake medicine worth $10.5 million were seized and 79 people were arrested. As part of Operation Pangea V, more than 18,000 illegal pharmacy websites were shut down.

DORNBUSH SCHAEFFER STRONGIN & VENAGLIA, LLP

747 Third Avenue | New York, NY 10017 | T: 212.759.3300 | www.dssvlaw.com