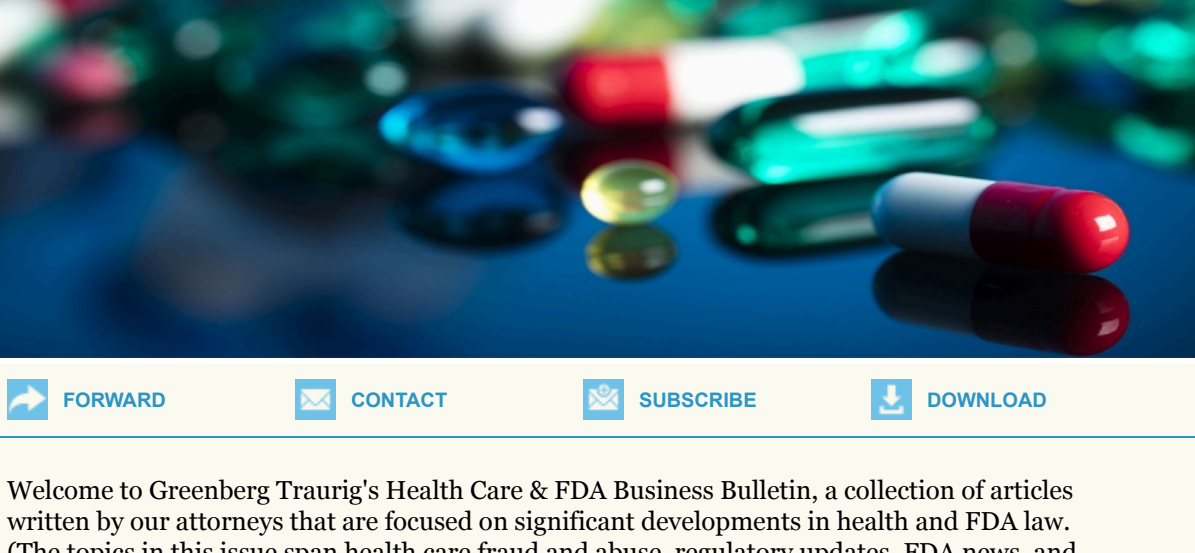



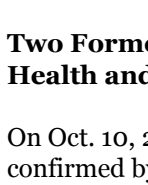


Health Care & FDA Practice | Newsletter


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Welcome to Greenberg Traurig's Health Care & FDA Business Bulletin, a collection of articles written by our attorneys that are focused on significant developments in health and FDA law. (The topics in this issue span health care fraud and abuse, regulatory updates, FDA news, and other health care topics.)

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NEWS

Two Former Greenberg Traurig Shareholders Now Serving as Appointees at Health and Human Services (HHS)

On Oct. 10, 2017, former Greenberg Traurig Health Care Shareholder **Eric D. Hargan** was confirmed by the Senate and appointed by the President as **Deputy Secretary** of HHS. Eric was also appointed as Acting Secretary of HHS, until the appointment of Alex M. Azar III on Jan. 24, 2018. Eric's government and legal experience spans nearly 25 years. Under the George W. Bush Administration, Eric held numerous positions at HHS, including Deputy General Counsel, Principal Associate Deputy Secretary, and Acting Deputy Secretary.

Following Eric's appointment, former Greenberg Traurig Health Care Shareholder **Robert P. Charrow** was confirmed by the Senate and appointed by the President as **General Counsel** of HHS on Dec. 21, 2017. Bob previously served as HHS Principal Deputy General Counsel under the Reagan Administration. As HHS General Counsel, Bob will supervise the chief counsel for the various agencies within the department, including the Food and Drug Administration, the Centers for Medicare & Medicaid Services, and the Public Health Service.

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HEALTH CARE FRAUD & ABUSE

Justice Department Outlines Factors That May Lead to Dismissal of More False Claims Act Cases

By [Francis J. Serbaroli](#)

An [internal memo](#) made public last month indicates that the U.S. Department of Justice (DOJ) may be moving to dismiss more False Claims Act (FCA) cases when it deems them meritless, opportunistic, or otherwise not in the government's interest. The memo states that DOJ receives approximately 600 new whistleblower (or relator) cases each year, and that when DOJ attorneys recommend not intervening in a relator's suit, they should take the further step of considering whether the government's interests would be served by seeking a dismissal. The memo lists seven factors for DOJ attorneys to consider as a basis for dismissal as further discussed below.

Continue reading [here](#).

Tips for Statistics in Health Care Enforcement Cases

By [Nathan Fish](#)

Dallas Bar Association's *Headnotes* – Government agencies and whistleblowers often use statistical sampling to recover money from health care providers and suppliers. This usually involves reviewing a random sample of a provider's claims, calculating an "error rate" based on purported errors in the sample claims, and extrapolating that error rate to all of the provider's claims within the same period. Although the sampling process can be quicker and less costly than reviewing all claims individually, it can artificially inflate overpayment and damage estimates if used incorrectly.

Attacking statistical methodologies can pay enormous dividends. For example, small victories on individual claims in the sample can have a big impact on the overall error rate. While statistical methodologies can be complex, these simple tips should help you shape a successful defensive strategy.

Continue reading [here](#) (p. 17).

OIG Approves Pharmacy's Benefit Program

By [Jennifer M. Little](#)

The Office of Inspector General for the U.S. Department of Health & Human Services (OIG) recently issued [Advisory Opinion 17-05](#), in which it approved a retail pharmacy chain's (Requestor's) proposal to allow federal health care program beneficiaries to participate in its paid membership benefit program. Membership to its benefit program would be open to anyone over the age of 18 who pays an annual membership fee and who provides certain personal information. Potential members would not be required to provide information about their insurance coverage or lack thereof.

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REGULATORY UPDATES

New York Limits No-Fault Payments to Out-of-State Medical Providers

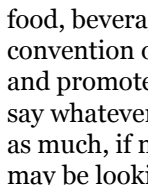
By [Francis J. Serbaroli](#)

New York State's Department of Financial Services (DFS) has finalized [new regulations](#) that may help to curtail the problem of steering patients injured in auto accidents in New York to receive high cost medical services from out-of-state medical providers.

As a no-fault state, automobile insurance policies in New York reimburse for medical services received by a policyholder who is injured in a car accident regardless of who is at fault. Payments for medical services provided to an injured person in New York are subject to a comprehensive fee schedule promulgated by DFS. In other words, the provider is not paid what the provider may normally charge, but an amount set by DFS. This fee schedule varies somewhat from region to region within New York.

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FDA NEWS

Keeping Trade Show Marketing Legal

By [Justin J. Prochnow](#)

Natural Products Insider – Trade shows have become ubiquitous in the dietary supplement, food, beverage, and cosmetic industries. Many times a month, there is a conference, convention or trade show in a different part of the country where companies can go to exhibit and promote their products. However, these shows are not a "free-for-all" for companies to say whatever they want to about their products. Claims made at trade shows are often under as much, if not more, scrutiny than claims made at retail or on the Internet. While companies may be looking to attract potential buyers from retailers or new customers, the halls are also filled with federal and state regulators, personnel from state attorneys general and district attorney offices, class action plaintiff lawyers, and competitors that are closely scrutinizing claims. Accordingly, companies must balance their desire to zealously promote their products with the need to ensure everything that is being said is permissible and supported with appropriate substantiation.

Continue reading [here](#).

Contract Manufacturing Agreements

By [Justin J. Prochnow](#)

Natural Products Insider – Believe it or not, some companies still conduct business without a formal written agreement, operating in the proverbial "handshake agreement" and a hodgepodge of purchase orders, emails and other communications, often leading to uncertainty and unwanted strife down the road. A well-crafted agreement executed between parties for the manufacture, supply and distribution of products can alleviate uncertainties and clarify the respective obligations of the parties.

Continue reading [here](#).

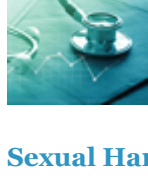
FTC's View on Claims Substantiation

By [Justin J. Prochnow](#)

Natural Products Insider – Advertising and labeling claims are a primary way companies try to grab consumer attention and distinguish one product from another. As the market becomes crowded, competition has increased and claims have become increasingly aggressive and, sometimes, overreaching. Companies must balance the desire to sell products against the fundamental principle that material claims must be substantiated with the appropriate level of support. If not, companies are at risk of action from regulatory agencies such as FTC and FDA, offices of state attorneys general, local district attorneys, competitors and, of course, plaintiffs' lawyers.

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OTHER

Sexual Harassment in the Health Care Workplace

By [Francis J. Serbaroli](#)

New York Law Journal – In recent months, many prominent persons have had career-ending allegations of sexual harassment brought against them. Those accused in these high-profile cases have come from media and entertainment, education, sports, government, finance, the arts, and other areas. The organizations with whom they were affiliated are scrambling to investigate these allegations, to do damage control, and to implement new policies and processes to demonstrate their zero-tolerance for such harassment. Questions are being raised as to whether the leadership of these organizations and their governing boards knew about the harassment, and if so, why appropriate action was not taken to stop it and prevent its recurrence.

Continue reading [here](#).

A Primer on Home Health Care Services

By [Francis J. Serbaroli](#)

New York Law Journal - The provision of health care services in patients' homes has grown exponentially over the past two decades. Originally, home care services were provided mostly by local not-for-profit agencies. Home care today has grown into a highly competitive multi-billion-dollar sector with both for-profit and not-for-profit providers. This column will discuss the various types of home health care services and the agencies that provide them in New York.

Continue reading [here](#).

Cybersecurity in the Health Care Sector

By [Francis J. Serbaroli](#)

New York Law Journal - As if it were not facing enough challenges, the health care industry is now becoming a more frequent target for hacking and ransomware by miscreants both domestic and foreign. Health care organizations have lagged behind other business sectors in protecting data, which is hard to understand given the extreme sensitivity of the data in their possession: personal and health information on individual patients; confidential information on internal quality assurance, risk management and utilization; results of clinical research on drugs, medical devices, and therapies; personal information on employees; sensitive internal financial information; confidential information on potential partnerships and deals with other organizations; and so on. Of even greater concern is the reality that hackers can interfere with webconnected medical equipment and devices and physically harm patients.

Continue reading [here](#).

Medical Marijuana and Employment Discrimination

By [Francis J. Serbaroli](#)

New York Law Journal - The jurisprudence that is developing in the wake of the legalization of medical marijuana by so many states is producing some very interesting court decisions addressing significant issues of first impression. In many of these cases, courts are faced with the continuing tension between state statutes legalizing marijuana for medical purposes, and federal laws that continue to criminalize its possession or use. A recent decision from the Supreme Judicial Court of Massachusetts points up some of these complexities.

Continue reading [here](#).

A Primer on Senior Living Facilities

By [Francis J. Serbaroli](#)

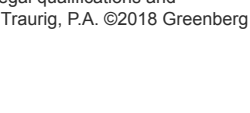
New York Law Journal – For generations, as people aged, too many of the frail elderly found themselves placed in nursing homes where many of them stayed for the remainder of their lives. Fortunately, today, there is a medical and social consensus that elderly people should be encouraged to stay in their own homes, and as needed, to receive appropriate support services for as long as they reasonably can. This is not only far more humane to the elderly, but in most cases it is their own clear preference. Moreover, being able to "age in place" can also reduce the sizable expenses associated with long-term nursing home care, particularly for the Medicaid program. For example, a senior citizen who has had a stroke may be hospitalized to receive treatment for the stroke, then spend some time in a skilled nursing facility to receive physical therapy and rehabilitative services, and then be returned home to continue recuperating with the assistance of a home health care services provider.

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