

Rx Ipsa Loquitur



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President's Message

Recognizing Excellence

*Steven Gray
ASPL President*

It was a pleasure to see Gary Cacciatore receive the well-deserved Joseph L. Fink III Founder's Award in November. One of the most important functions of our Society is to recognize and reward excellence in pharmacy and law. However, if you look at the more extended announcement on page 4 of this issue, it will be apparent that this award is not always an annual presentation. This is not due to lack of deserving recipients from among ASPL's 400-plus members. It is because our members sometimes fail to take the time to submit nominations in a given year.

So, here's my plea to you - my fellow ASPL members. Please do your part in the recognition of excellence by our Society by nominating potential recipients - of course according to the timelines for nominations for our two major awards:

- **Joseph L. Fink III Founders Award** - recognizes sustained and outstanding service and contributions to the professions of pharmacy and law. Any member may nominate an individual and the nominee does not need to be a current ASPL member. Nominations for 2016, including documentation, should be submitted to ASPL by **June 30, 2016**.
- **Larry M. Simonsmeier Writing Award** - recognizes outstanding scholarship related to pharmacy law. Members or other interested parties may nominate any paper for the 2016 award that was published or accepted for publication in any English-language peer-reviewed journal (including law reviews) from January 2013 through December 2015. Authors may submit their own publications, including articles in press. The deadline for the 2016 award is **June 30, 2016**.

Complete information about these awards is available on the ASPL webpage, under the Awards tab. Please take part in this important activity of ASPL.

Department of Justice Policy

Be Careful What You Wish For: DOJ's Recent Guidance Prioritizing Prosecution Of Individuals For Alleged Corporate Wrongdoing

By Ronald J. Friedman

On September 9, 2015, in an official policy memorandum attracting national attention, the United States Department of Justice (DOJ) announced a new policy and directive in regard to its pursuit of corporate wrongdoing at all levels of business. The memorandum, titled "Individual Accountability for Corporate Wrongdoing,"¹ authored by Deputy Attorney General Sally Yates, directs federal prosecutors throughout the country to prioritize the prosecution of individuals over that of the corporation in all instances, and to target such individuals for criminal prosecution any time a corporate plea is considered. On November 16, 2015, the Yates memorandum was fully implemented in revisions to the Department of Justice's United States Attorneys' Manual (USAM), which is routinely relied upon by federal prosecutors in deciding whether to bring civil and criminal charges against individuals and corporate entities for alleged wrongdoing. The USAM,² which creates no rights on behalf of individuals, provides instructions to federal prosecutors throughout the country as to who to charge and how to resolve cases.

The Yates memorandum speaks in newly energized terms regarding the DOJ's desire that individuals be the "focus" of the government's investigation from its "inception," "regardless of whether the investigation begins civilly or criminally." The memorandum states that absent "extraordinary circumstances" individuals should be charged criminally and/or civilly, anytime a matter is being resolved with the corporation. The memorandum emphasizes that corporate employees should be targeted for civil actions and fines in cases of corporate wrongdoing regardless of the individual's ability to pay. Regarding criminal exposure, the memorandum provides that any decision to decline criminal prosecution of an individual must be "memorialized" and "approved in writing" by the United States Attorney in the district of investigation or by higher-ups in the Justice Department.³ In addition, the policy instructs DOJ civil and criminal enforcement attorneys to routinely communicate with one another regarding the possibility of parallel criminal and civil proceedings, so that each can be leveraged to achieve maximal results.

This new policy, since formally adopted through several revisions to the USAM, applies to every United States Attorney's Office across the country and every litigating arm of the DOJ. It applies to all pending and future investigations. It creates, for the first time, an affirmative obligation that prosecutors pursue individual culpability in all cases of corporate malfeasance and requires the evaluation and resolution of cases against individuals in conjunction with the resolution of corporate cases. It forbids prosecutors from providing releases or immunity for individuals upon resolution of charges against the corporate entity, unless the reason for doing so is memorialized and approved by the U.S. Attorney in the district where the matter is pending or by other high-ranking DOJ officials located in Washington, D.C. It should be noted that although the directive speaks in terms of "corporate" malfeasance, the DOJ has made clear that its new policy applies with equal force to all types of business entities, including partnerships and sole proprietorships.⁴

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DOJ Policy

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The DOJ has expressly acknowledged that this new policy constitutes a shift in emphasis. Assuredly, it does. The shift is away from the measured informal discretion traditionally accorded local federal prosecutors to determine how best to pursue instances of corporate wrongdoing, in favor of a structure that leverages the prosecution of the individual at every turn by forcing individual prosecutors to write a memorandum justifying any decision to decline to prosecute officers, directors, managers and employees, and requiring approval by the United States Attorney which runs the local office or a higher-up at the Justice Department for any decision not to prosecute. In truth, no Assistant United States Attorney is going to relish the extra work and effort involved with justifying decisions not to prosecute, especially where your commanders in D.C. have suggested the goal is just the opposite. Thus, we have put in place a system which incentivizes and will reflexively result in more prosecutions of individuals at all levels anytime corporate misconduct is found.

In addition, the new policy instructs that any corporation wishing to better its position by cooperating with the government will have to name all names and identify all persons involved in any potential wrongdoing in order to receive any credit for such cooperation. As stated by DAG Yates in comments regarding the new policy:

- Effective immediately, we have revised our policy guidance to require that if a company wants any credit for cooperation, any credit at all, it must identify all individuals involved in the wrongdoing, regardless of their position, status or seniority in the company and provide all relevant facts about their misconduct. It's all or nothing.
- This threshold requirement of complete cooperation as to individuals not only governs criminal investigations, but applies to civil investigations as well. Companies will be expected to provide

the same type of information about individuals if they want any consideration on the civil side, including how a case is charged or resolved and whether we bring action against a parent or its subsidiary. Similarly, it will be the department's position going forward that in order to qualify for the reduced damages provision under the False Claims Act, the company must identify any culpable individuals and provide all material facts about those individuals.

This new policy comes in response to much public criticism of the Justice Department for its recent lack of prosecution of corporate higher-ups. However, in enacting the policy and revisions to the USAM, the government has put in place a system which leverages the prosecution of corporate actors at all levels. Further, the government has done so at a time of increasing public concern with "overcriminalization," where many are legitimately asking whether we are drawing upon our criminal justice system too much to resolve complex issues, where we have witnessed a veritable explosion of our prison population beyond that of any modern democracy, and where we are paying a staggering 30% of the Department of Justice's annual budget simply to house people. An intelligent response to crime, including crime in the corporate sector, requires that we see matters in a broader context and look at the collateral consequences of what we are doing, which often is not helping anything or anyone.

Political comments aside, there is no question that this policy should cause serious concern to corporations, especially in the health and pharmaceutical sectors, where DOJ has shown a recent penchant and hunger for enforcement. This change in policy needs to be carefully considered internally by a corporation and by its inside and outside counsel whenever regulatory issues arise. For example, the corporation will need to evaluate most carefully the need for individual counsel for potential subjects of the investigation, including employees, since the government is making clear that

many in the corporate ladder will be potential targets of the investigation. This calculation should be performed regardless of whether an investigation appears civil or criminal, since they can easily shift, or be both. In addition, corporations will have to carefully consider any thoughts of cooperating with the government and what this may mean to individuals who may be impacted, as it is clear that a corporate fine will not be sufficient to satisfy the government.

One wonders how this new policy may affect the current practice of allowing a corporation to resolve legal exposure by agreeing to a fine and corporate integrity program – which heretofore was regarded as a fairly effective way of addressing malfeasance and preventing its recurrence. Is this no longer regarded an effective means of addressing? Must "heads roll" and the criminal process be invoked in order to achieve finality? Many questions in the microcosm of pharmacy practice are also raised: Will the pharmacist-in-charge of a pharmacy where lax supervision has led to significant diversion of controlled substances, or where employees are found to have routinely billed for capsules instead of tablets of a generic drug to circumvent MAC pricing now risk criminal prosecution? Will direct managers and higher-ups be increasingly in harm's way?

Whether or not this new emphasis by the DOJ will be effective in increasing legal compliance is too early to tell. In the meantime, however, executives and employees are well advised to expect that their individual conduct will be increasingly scrutinized as part of any ongoing federal investigation. One should be mindful of this new emphasis and pay utmost attention to any government inquiry, civil or criminal, and have an effective strategy in place to determine how best to address. Creativity and carefulness in formulating a response to government inquiry and investigation is paramount.

Ronald J. Friedman, JD, is a shareholder at Karr Tuttle Campbell in Seattle and was a federal prosecutor for 22 years before entering private practice.

1. Yates SQ. Memorandum for Assistant Attorneys General et al., USDOJ, Office of Deputy Attorney General, September 9, 2015; <http://www.justice.gov/dag/file/769036/download>, accessed 10/23/15.
2. See, United States Attorneys' Manual, Chapters 9-28.000 and 4-3.100.
3. As stated in USAM Section 9-28.200: "If a decision is made at the conclusion of the investigation to pursue charges or some other resolution with the corporation but not to bring criminal or civil charges against the individuals who committed the misconduct, the reasons for that determination must be memorialized and approved by the United States Attorney or Assistant Attorney General whose office handled the investigation, or their designees.
4. As stated in USAM Section 9-28.200: "While these guidelines refer to corporations, they apply to the consideration of the prosecution of all types of business organizations, including partnerships, sole proprietorships, government entities, and unincorporated associations."

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2015 Joseph L. Fink III Founders Award

The 2015 Joseph L. Fink Founders Award was presented to Gary Cacciatore at ASPL's 26th Developments in Pharmacy Law Seminar in Miami, Florida in recognition for his sustained and outstanding service to the professions of pharmacy and law.

Gary has a long history with ASPL and the pharmacy and law professions. He is a dedicated pharmacist and attorney and is a past president of ASPL. His commitment to this organization during the period he served in leadership is evident in his guiding ASPL during an economically difficult financial time. Gary's dedication to the advancement of ASPL and its members is a testament to his vision and strength. He remains committed to ASPL and its members through voluntary participation and encouragement of membership in the organization.

Gary's impact goes far beyond ASPL. He has co-authored the seminal textbook on Texas Pharmacy Law and continues to provide a review course for pharmacy students and pharmacy license transfer applicants to Texas. He continues to be involved in lecturing on Texas pharmacy law when asked by academic institutions in Texas.

He has served the State of Florida on many committees formed to address often complicated legal-regulatory matters and has served as their Chair, including the Drug Wholesale Advisory Board and most recently the Prescription Drug Abuse Committee of the Florida Board of Pharmacy.

The Joseph L. Fink III Founders Award was established in 2004 to recognize sustained and outstanding service and contributions to the professions of pharmacy and law. The award is named for Joseph L. Fink, III, who founded ASPL in 1974 and served as the Society's first president.

Previous Joseph L. Fink Award Recipients Include:

2012 – William E. Fassett	2008 – William L. Markus & David P. Work
2011 – Norman A. Campbell	2006 – Joseph G. Valentino
2010 – Kenneth R. Baker	2004 – Joseph L. Fink III
2009 – Jesse C. Vivian	

