

## Hyung P. Steele

Partner

Philadelphia

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Pharmaceutical and medical device clients trust Hyung in their defense of product liability litigation and civil and criminal investigations involving alleged fraud and abuse, as well as to guide them in evaluating internal compliance programs and to conduct internal investigations.

### OVERVIEW

Hyung has deep experience defending pharmaceutical and medical device clients in product liability and personal injury litigation, including in federal multidistrict litigation and coordinated state court proceedings, and class actions. He also represents pharmaceutical companies and individuals in parallel federal criminal, civil, and state attorney general investigations. Hyung's practice also includes substantial experience partnering with pharmaceutical and medical device clients to evaluate their internal corporate compliance programs and conducting internal investigations. This includes working with clients to update their compliance policies, and developing focused investigator training programs and investigation support materials. Hyung also counsels clients on regulatory compliance and risk mitigation strategies, including advising on promotional claims, competitor issues and conducting risk assessments.

Hyung maintains an active pro bono practice. He has handled §1983 prisoner civil rights cases, asylum appeals to the Third Circuit, and has provided assistance to the Immigration Domestic Violence Pro Bono Practice Group. In addition, he serves as a volunteer for a Philadelphia homeless shelter each winter.

Hyung is a passionate advocate for inclusion. He is a founder and past co-chair of the firm's AAPI Affinity Network. He was selected for the 2013 Fellows Program of the Leadership Council on Legal Diversity and is a past member of LCLD's Advocacy Group Committee. The LCLD's Fellows Program is intended to help diversify the legal profession by producing attorneys with strong leadership and networking skills who enjoy relationships with industry leaders and who are committed to fostering inclusion within their individual institutions. Hyung is an active participant in the firm's associate mentor program and LCLD's law school mentor program.

### REPRESENTATIVE MATTERS

- Served as defense counsel for a specialty pharmaceutical company in a consumer class action involving false advertising claims regarding its thyroid medication. The lawsuit alleged that certain batches of the thyroid medication contained inconsistent amounts of the active ingredient, making them ineffective or unsafe.
- Provided national representation for pharmaceutical and medical device companies in products liability, consumer fraud, and class actions filed in multidistrict litigation, coordinated state court proceedings, and

individual cases throughout the U.S. Specific experience includes defending claims involving antipsychotics, antidepressants, diabetes treatments, spinal and surgical medical devices, and opioids.

- Represented pharmaceutical companies and employees in civil and criminal investigations brought by federal authorities related to sales and marketing practices of marketed products.
- Represented a pharmaceutical company in a sweeping, industry-wide investigation by federal authorities into donations to charitable assistance foundations that provide financial assistance to Medicare patients.
- Represented a pharmaceutical company in defense of an economic loss class action alleging the purchase of adulterated and “worthless” product.
- Represent an individual in a parallel DOJ and SEC insider trading investigation.
- Represented pharmaceutical companies in litigation involving adverse events in clinical trials.
- Represented a Pest Control Company in defense of a wrongful death claim.
- Represented a medical device company in defense of a product liability claim alleging significant burn injuries following an aesthetic treatment.
- Represented a cosmetic distributor in defense of a product liability claim.
- Defended multiple Pennsylvania nursing homes in state Attorney General investigations.
- Counseled and defended pharmaceutical companies in state Attorney General investigations and inquiries by congressional committees.
- Defended a pharmaceutical company in a qui tam action brought to recover damages under the federal False Claims Act, various state False Claims Acts and the Anti-Kickback Statute.
- Conducted early case assessments and risk assessments for pharmaceutical products subject to potential litigation, including evaluating sales and marketing practices and speaker programs.
- Conducted domestic and global internal compliance investigations for multiple pharmaceutical and medical device companies involving sales and marketing issues, FCA retaliation allegations, bribery and kickback allegations, scientific authorship disputes, conflicts of interest, and other company policy and code of conduct violations.
- Advised pharmaceutical companies on regulatory compliance and risk avoidance, including prophylactic counseling on sales and marketing and competitor issues for marketed products and investigational new drugs.
- Conducted litigation risk due diligence for potential acquisitions by pharmaceutical companies.
- Conducted an independent investigation into acts of violence at a public high school.

## **AWARDS**

- *Pennsylvania Rising Stars* (2015)
- *Legal 500 United States* (2014)

## **TOP AREAS OF FOCUS**

- Health Care + Life Sciences
- Pharmaceutical + Medical Device Litigation + Counseling
- Product Liability
- White Collar Litigation + Investigations

## **ALL AREAS OF FOCUS**

- FDA Regulatory + Risk Management Counseling
- False Claims Act + Other Whistleblower Actions

- [Fraud + Abuse Litigation + Investigations](#)
- [Health Care + Life Sciences](#)
- [Litigation + Trial](#)
- [Pharmaceutical + Medical Device Litigation + Counseling](#)
- [Product Liability](#)
- [State Attorneys General](#)
- [White Collar Litigation + Investigations](#)

## **PROFESSIONAL/COMMUNITY INVOLVEMENT**

- Past member, Board of Directors, Public Interest Law Center

## **EDUCATION AND CERTIFICATIONS**

### **EDUCATION**

- Villanova University Charles Widger School of Law, J.D., *cum laude*, 2003, member, Villanova Moot Court Executive Board
- Kenyon College, B.A., 1997, English and economics

### **BAR ADMISSIONS**

- New Jersey
- Pennsylvania

### **COURT ADMISSIONS**

- U.S. Court of Appeals, Second Circuit
- U.S. Court of Appeals, Third Circuit
- U.S. District Court, Eastern District of Pennsylvania

## **SPEAKING ENGAGEMENTS**

- Speaker, "[Ethical Oversight and Best Practices: AI Integration in Compliance Departments](#)," ACC Greater Philadelphia's Ethics & Compliance CLE Webinar, March 19, 2025.
- Speaker, "[Breaking Boundaries – A Conversation with Kelly Mi Li from Bling Empire](#)," Troutman Pepper, June 8, 2021.

## **PUBLICATIONS**

- Co-author, "[A Model's Credibility Is in the Details: FDA Draft Guidance on the Use of AI Models in Drug and Biological Product Development](#)," *Troutman Pepper Locke*, February 12, 2025.
- Co-author, "[FDA Finalizes Guidance on Communications Regarding Unapproved Uses of Medical Products](#)," *Troutman Pepper Locke*, January 22, 2025.
- Co-author, "[FDA Issues New Draft Guidance for Unapproved Use Communications](#)," *Troutman Pepper*, October 25, 2023.

## **MEDIA COMMENTARY**

- Mentioned, “Acella’s \$46.5M Drug Recall Settlement Gets Initial Signoff,” *Law360*, February 7, 2024.