

**Curriculum Vitae – John W.M. Claud**  
**Hyman, Phelps & McNamara, P.C.**

Mr. Claud counsels FDA-regulated entities on litigation, enforcement, and compliance matters including FDA inspections, Form 483s, Warning and Untitled Letters and Consent Decrees, internal investigations, and data privacy concerns. He also advises clients on matters related to compliance with the Controlled Substances Act and DEA regulations, and matters involving drug compounding, telehealth, and telemedicine.

Mr. Claud is a 15-year veteran of the Department of Justice, and prior to joining Hyman Phelps, he most recently served as the Assistant Director of the Consumer Protection Branch, where he led the Corporate Compliance and Policy Unit. Mr. Claud has prosecuted and supervised complex criminal and civil trial litigation and investigations under the Food, Drug and Cosmetic Act, Federal Trade Commission Act, Consumer Product Safety Act, and Federal data privacy laws. He also held leading roles in DOJ's response to three recent and significant national health crises, including the COVID -19 pandemic. Mr. Claud is an accomplished trial lawyer, having started his career as an Assistant District Attorney in Manhattan before joining DOJ. He is a frequent public speaker on matters of government enforcement strategies under the FDCA as well as corporate compliance best practices.

**Education**

- Catholic University of America Columbus School of Law, Washington, DC - Juris Doctor, *cum laude* (2000)
- University of Colorado, Graduate School of Public Affairs, Denver, CO - Master of Criminal Justice (1993); Honored as Outstanding Student of Criminal Justice Program
- Trinity College, Hartford, CT - Bachelor of Arts (1991)

**Affiliations**

Member, Food and Drug Law Institute

**Governmental Policy and Leadership**

- Supervised the Consumer Protection Branch's Corporate Compliance and Policy Unit.
- Directed DOJ's national oversight of FDCA criminal cases, including the national enforcement response to FDCA violations related to the COVID pandemic.
- Directed DOJ's criminal investigative response to the 2019 EVALI vaping crisis.

**Government Enforcement Litigation and Trial Work**

- Co-lead counsel and then supervisor of investigation and subsequent indictment in groundbreaking, \$900 million telemedicine prescription drug fraud scheme.
- Supervised negotiated resolution of permanent injunction and consent decree of pharmaceutical manufacturer accused of introducing misbranded and adulterated drugs into interstate commerce.
- Member of investigative and trial team in the prosecution stemming from 2012 national meningitis outbreak caused by adulterated drugs produced at a Massachusetts compounding pharmacy that resulted in 100-plus deaths and hundreds of infections nationwide. Co-counsel

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during 10-week jury trial of the lead defendant, which resulted in convictions on 57 felony counts, including Racketeering and Mail Fraud.

- Lead counsel in investigation, indictment, and prosecution of counterfeit prescription drug smuggling ring, resulting in numerous convictions.

**Honors & Awards**

- 2022 National Health Care Anti-Fraud Association Investigation of the Year for work on telemedicine prescription drug fraud scheme.
- 2020 Department of Justice Civil Division Special Commendation for national coordination of COVID fraud work.
- 2020 Executive Office of United States Attorneys Director’s Award for work on prosecutions relating to the 2012 fungal meningitis outbreak.
- 2020 FDA Special Citation for work on prosecutions relating to the 2012 fungal meningitis outbreak.
- 2019 National Health Care Anti-Fraud Association Investigation of the Year Award - Honorable Mention for work on prosecutions relating to the 2012 fungal meningitis outbreak.

**Recent Speaking Engagements (List all recent speaking engagements. Please include a link if more information is available on the current HPM website)**

- Panelist, 2023 American Conference Institute Advanced Forum on Defending FDA-Regulated Consumer Products Class Actions
- Panelist, 2023 FDLI Enforcement, Litigation and Compliance Conference
- Panelist, 2022 InformaConnect Hub and Specialty Pharmacy Models West Conference
- Featured Speaker, 2022 InformaConnect Pharmaceutical Compliance Conference
- Panelist, 2021 FDLI Advertising and Promotion for Medical Products Conference
- Panelist, 2021 FDLI Digital Health Technology and Regulation Conference
- Panelist, 2021 FDLI Enforcement, Litigation and Compliance Conference
- Panelist, 2021 American Conference Institute Advanced Summit on Food Law
- Panelist, 2020 FDLI Cannabis Regulation Conference
- Featured Speaker, 2020 InformaConnect Compounding Pharmacy Compliance Conference
- Panelist, 2020 FDLI Advertising and Promotion Conference
- Panelist, 2019 FDLI Food Safety and Enforcement Conference
- Panelist, 2019 PCF Annual Pharmaceutical and Medical Device Compliance Congress
- Panelist, 2019 FDLI Annual Conference
- Panelist, 2019 FDLI Food Safety and Enforcement Conference
- Panelist, 2018 DOJ National Health Care Fraud and Opioid Training Conference
- Featured Speaker, 2018 CBI Compounding Pharmacy Compliance Conference
- Panelist, 2018 FDLI Drug Quality Security Act Conference

**Articles & Publications**

*Responding to Defense Demands for Assistance in Large ESI Criminal Cases*, United States Attorney’s Bulletin, Vol. 66, No. 1 (January 2018)