

FOR IMMEDIATE RELEASE

Contact AHLA: Stefan Bradham
Senior Director, Marketing and Communications
sbradham@healthlawyers.org

Contact Seton Hall Law: Janelle Costa
Director of Communications
Janelle.costa@shu.edu

AHLA PUBLISHES SECOND EDITION OF COMPLIANCE MANUAL IN CONJUNCTION WITH SETON HALL LAW

WASHINGTON, DC (JULY 23, 2019)—Published by the American Health Lawyers Association (AHLA) in collaboration with Seton Hall Law School's Center for Health & Pharmaceutical Law & Policy, the second edition of *Pharmaceutical and Medical Device Compliance Manual* synthesizes what can be an overwhelming quantity of authority into understandable analysis and practical action for those who create, manage, and monitor effective life science compliance programs in today's complex enforcement and business environment.

This *Manual* will enable compliance professionals and lawyers to understand:

- The government's expectations of an effective compliance program and ethical business practices
- How the government discovers potential enforcement actions
- The government's approach to pursuing such actions
- What behaviors can constitute mitigating factors for a company in the event of a legal violation

"Pharmaceuticals are once again the focus of federal and state scrutiny," said Rob Anderson, AHLA's Senior Director of Publishing. "This *Manual* provides manufacturers with the tools to build the robust and effective compliance program needed in the current regulatory environment."

"We are very pleased to have been able to bring together some of the leading authorities in pharmaceutical and medical device law and compliance to produce the second edition of the manual," said Professor Carl H. Coleman, Seton Hall Law. "Their analysis and insights will be equally useful to both newcomers to the field and experienced practitioners."

Additionally, the second edition includes new and updated analysis addressing changes in fraud enforcement; communications with patients, physicians, formulary committees, and others; regulation of biologics, software, drug-device combination products, and human cells; The 21st Century Cures and Right to Try Acts; the impact of privacy laws including GDPR; transparency; and compliance in the era of big data.

Pharmaceutical and Medical Device Compliance Manual is available to order through AHLA's store on the LexisNexis website for both [members of AHLA](#) and the broader [health law professionals community](#).

For a high-resolution image of the book cover, editor/author headshots, or interview inquiries, please contact AHLA.

###

Second Edition Editors/Authors:

Ela Bochenek, Carl H. Coleman, Amy Matey, Editors

Marc Adler, Joseph S. Calarco, Bret A. Campbell, Colleen A. Conry, Scott Cunningham, Scott D. Danzis, Sujata Dayal, Marc I. Eida, Jacob T. Elberg, Brett R. Friedman, Gary F. Giampetruzzi, Christopher R. Hall, Patrick M. Hromisin, Mark Krueger, Bruce A. Levy, Veronica Lopez, Joseph W. Metro, Gregg Shapiro, Brian P. Sharkey, Anna Spencer, Robert E. Wanerman, Constance A. Wilkinson, Christopher D. Zalesky, Authors

About AHLA:

The mission of AHLA is to provide a collegial forum for interaction and information exchange to enable its members to serve their clients more effectively; to produce the highest quality non-partisan educational programs, products, and services concerning health law issues; and to serve as a public resource on selected health care legal issues. For more information, visit www.healthlawyers.org.

About Seton Hall Law School's Center for Health & Pharmaceutical Law & Policy:

Founded in 1951 and located in Newark, Seton Hall University School of Law is dedicated to preparing students for the multiplicity of pathways open to professionals with a legal education in a world transformed by technology. The Law School also offers a robust selection of online and live compliance programs in privacy, cybersecurity, financial services, and health & life sciences for law and graduate students, as well as mid-career professionals. The Law School's Center for Health & Pharmaceutical Law & Policy exists primarily to educate students, lawyers, and health care industry professionals regarding the extraordinarily complex set of laws that govern patients, health care providers, manufacturers, and suppliers. The Center is a leader in providing compliance education and training on the wide-ranging state, federal, and international mandates that apply to the development, safety, use, and promotion of drugs and devices. For more information, please visit law.shu.edu/compliance/health.