

Donald D. Ashley

Executive Vice President, Regulatory Compliance



BACKGROUND

- Six years as Director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research (CDER)

EXPERIENCE

- 25 years of experience as an expert in compliance and enforcement matters

AWARDS

- Recipient of multiple FDA awards for exceptional and superior work, including from the Commissioner in 2018, 2019, 2021, and 2022
- Recipient of multiple awards from the Department of Justice for exceptional and outstanding service, including from the Assistant Attorney General in 2008 and 2015

Don Ashley joined Greenleaf Health after a distinguished 25-year career at the Food and Drug Administration (FDA) and the Department of Justice (DOJ), including six years as Director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research (CDER).

As Director of CDER's Office of Compliance, Don led a staff of over 400 lawyers, scientists, consumer safety officers, pharmacists, and physicians. He oversaw development and implementation of the FDA's entire breadth of drug compliance and enforcement measures, including for manufacturing quality, current good manufacturing practice, good clinical practice, data integrity, clinical trial oversight, pharmacovigilance, drug supply chain security, compounding, over-the-counter monograph compliance, drug import and export, and unapproved drug compliance, among other areas. Don led all drug compliance actions taken by the FDA following inspection, as well as all grants of regulatory discretion in drug shortage cases. As an executive member of CDER's Drug Risk Management Board, Don helped guide the Agency's approach to some of most difficult drug safety issues over the last several years, including for nitrosamine and benzene impurities. In addition, Don served as one of a small group of senior agency officials who liaised with the generic drug industry to implement the Generic Drug User Fee Act program.

Before joining the FDA, Don spent nearly two decades at DOJ in both the Civil and Criminal Divisions, prosecuting violations of the Food, Drug, and Cosmetic Act among other criminal statutes, as well as managing and directing investigations on both a national and international level. During his time with the Civil Division's Office of Consumer Litigation (now the Consumer Protection Branch), he prosecuted complex schemes to defraud consumers and/or federal agencies such as the FDA. Later, Don served in Asia as the senior DOJ official responsible for managing international law enforcement cooperation on behalf of the United States with several countries, including the Philippines, Singapore, and Indonesia. Don also represented DOJ in Italy as the senior official responsible for facilitating closer cooperation between Italy and the United States in criminal investigations and prosecutions.

Previously, Don worked as a senior litigation associate with a major D.C. law firm, often representing clients under investigation for FDA-regulated activities. Don also served on active duty as an Army captain assigned to the Office of General Counsel, Department of the Army.

Don earned his J.D. from Harvard Law School and an A.B., *magna cum laude*, from John Carroll University.