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Peter Barton Hutt
Senior Counsel

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Education

- Yale College, B.A.
- Harvard Law School, LL.B.
- New York University School of Law, LL.M. in Food and Drug Law

PRACTICES

- Food and Drug Law
  - Cosmetics
  - Dietary Supplements
    - New Dietary Ingredients
    - Structure/Function Claims
  - Food
    - Food Additives and GRAS
    - GMP and HACCP
    - Medical Food
    - Product Claims
  - Human Pharmaceuticals
    - Biological Products
    - Nonprescription Drugs
    - Prescription Drugs
  - Medical Devices
    - 510(k) Notifications
    - PMA Applications
    - In Vitro Diagnostics
  - FDA Dispute Resolution
    - Informal

Peter Barton Hutt is a Senior Counsel in the Washington, DC law firm of Covington & Burling LLP, specializing in Food and Drug Law. He began his law practice with the firm in 1960 and, except for his four years in the government, has continued at the Firm ever since.

From 1971 to 1975 Mr. Hutt was Chief Counsel for the Food and Drug Administration. During his tenure as FDA Chief Counsel, Mr. Hutt led the transformation of the agency from outdated law enforcement to modern administrative law. He promulgated regulations to implement the review of GRAS food ingredients, to require nutrition labeling for half the food supply, to define "imitation" food, to establish the emergency permit controls for low acid canned food, and to modernize food standards; to implement the prescription drug requirements of the Drug Amendments of 1962 following a sweeping victory in four Supreme Court cases, to create the OTC Drug Review for nonprescription drugs, and to establish the doctrine that a physician may lawfully prescribe an FDA-approved drug for an unapproved

- Formal
- Enforcement
  - Imports
  - Inspections
  - Warning Letters
  - Court

- Government Affairs
  - Congressional Relations
  - FDA Advocacy
  - Legislative Testimony

- Strategic Risk and Crisis Management

REPRESENTATIVE PUBLICATIONS

The Federal Food, Drug, and Cosmetic Act

- "Food and Drug Law: Cases and Materials," *Foundation Press* (4th edition 2014), Co-Author.

FDA History

- "Historical Themes and Developments at FDA Over the Past Fifty Years, " FDA In the 21st Century Chapter 1 at 17 (2015).
- "The State of Science at the Food and Drug Administration," *60 Administrative Law Review 431* (Spring 2008).
- "Turning Points in FDA History," *Chapter 2 in Perspectives on Risk and Regulation* (2007).
- "FDA Comes of Age: A Century of Change," *Chapter 3 in FDA: A Century of Consumer Protection* (2006).
- "A Brief History of FDA Regulation of Exports," *Chapter 1 in Export Expertise: Understanding Export Law For Drugs, Devices and Biologics* (1998).
- "The Food and Drug Administration Modernization Act of 1997," *52 Food Technology 54* (May 1998).
- "The Transformation of United States Food and Drug Law," *60 Journal of the Association of Food and Drug Officials 1* (September 1996).

Food

- "U.S. Government Regulation of Food with Claims for Special Physiological Value," *Chapter 16 in Essentials of Functional Foods* (2001).
- "Regulation of Food Additives in the United States," *Chapter 8 in Food Additives* (2d edition 2001).
- "A Brief History of FDA Regulation Relating to the Nutrient Content of Food," C*hapter 1 in Nutrition Labeling Handbook* (1995).
- "Government Regulation of Health Claims in Food Labeling and Advertising," *41 Food Drug Cosmetic Law Journal 3* (January 1986).
- "A History of Government Regulation of Adulteration and Misbranding of Food," *39 Food Drug Cosmetic Law Journal 2* (January 1984), Co-Author.

(off-label) use; to create a process for reevaluating the safety and effectiveness of all biological products that had been licensed since 1902; to rationalize the application of the Delaney Anticancer Clause to animal drugs; to require ingredient labeling for cosmetics and premarket safety substantiation for all cosmetic ingredients; and to prepare FDA for enactment of the Medical Device Amendments of 1976. He created the requirement of preambles for all proposed and final FDA regulations, initiated the use of guidelines (now called guidance) to establish informal FDA policy, established the use of regulatory letters (now called warning letters) as an inexpensive and efficient compliance approach, and persuaded the Solicitor General to defend the stringent FDA criminal enforcement policy before the Supreme Court in *United States v. Park*. Just before leaving FDA, he wrote the comprehensive proposed procedural regulations that govern all FDA administrative action to this day.

Since 1994, he has taught a full course on Food and Drug Law during Winter Term at Harvard Law School. Harvard Law School held a symposium on January 17, 2013, "Celebrating Peter Barton Hutt's 20 Years (thus far) at HLS". He taught the same course at Stanford Law School during Spring Term in 1998. He is the co-author of *Food and Drug Law: Cases and Materials* (Foundation Press, 1st edition 1980, 2d edition 1991, 3d edition 2007, 4th edition 2014, 5th edition to be published in 2022) and has published more than 175 book chapters and articles on Food and Drug Law and on health policy. He is a member of the Editorial Advisory Board of the Food and Drug Law Journal.

Mr. Hutt has extensive experience working on FDA legislation. Before joining FDA, he worked on the Drug Amendments of 1962, the Controlled Substances Act of 1970, and the Poison Prevention Packaging Act of 1970. While at FDA he was responsible for the legislation that became the Drug Listing Act of 1972, the Consumer Product Safety Act of 1972, and the Medical Device Amendments of 1976. Since 1976, he has participated in the drafting of major legislation amending the Federal Food, Drug, and Cosmetic Act. Representing the Pharmaceutical Research and Manufacturers of America (then called the Pharmaceutical Manufacturers Association), Mr. Hutt testified before Congress and worked with congressional staff on the Drug Regulation Reform Act of 1978, the Orphan Drug Act of 1983, and the Drug Price Competition and Patent Term Restoration Act of 1994, and he worked with congressional staff on the Drug Export Amendments Act of 1986, the Nutrition Labeling and Education Act of 1990, the Prescription Drug User Fee Amendments of 1992, the

Dietary Supplements

- "The History and Future of the Dietary Supplement Health and Education Act," *14 National Products Insider, No. 11, at 16* (October 5, 2009).
- "FDA Statutory Authority to Regulate the Safety of Dietary Supplements," *31 American Journal of Law & Medicine 155* (2005).

Drugs

- "The Evolution of Federal Regulation of Human Drugs in the United States: An Historical Essay," 44 American Journal of Law and Medicine 405 (2018).
- "Commemorating the 50th Anniversary of the Drug Amendments of 1962," 68 Food and Drug Law Journal 449 (2013)(with Robert Temple, M.D.).
- "The Regulation of Drug Products by the United States Food and Drug Administration," *Chapter 24 in the Textbook of Pharmaceutical Medicine,* (7th edition 2013).
- "Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984," *40 Food Drug Cosmetic Law Journal 269* (July 1985)(with Ellen J. Flannery).

Cosmetics

- "The Legal Distinction in the United States Between a Cosmetic and a Drug," *Chapter 34 in Cosmeceuticals and Active Cosmetics* (3d edition 2016).
- "A History of Government Regulation of Adulteration and Misbranding of Cosmetics," *Chapter 1 in Cosmetic Regulation in a Competitive Environment* (2000).

Medical Devices

- "A Brief History of the Regulation of In Vitro Diagnostic Products," C*hapter 1 in In Vitro Diagnostics: The Complete Regulatory Guide* (2010).
- "A History of Government Regulation of Adulteration and Misbranding of Medical Devices," *44 Food Drug Cosmetic Law Journal 99* (March 1989).

Teaching Food and Drug Law

"Food and Drug Law: Journal of an Academic Adventure," *46 Journal of Legal Education 1* (March 1996).

Dietary Supplement Health and Education Act of 1994, and the Export Reform and Enhancement Act of 1998. At the request of the House and Senate staff, he drafted and worked on the Food and Drug Administration Modernization Act of 1997. He has continued to work on FDA-related legislation since then, including the Prescription Drug User Fee Act of 1992 and the subsequent PDUFA laws. Most recently, he worked on the 21st Century Cures Act of 2016. He has testified before the House and Senate more than 100 times either as counsel accompanying a witness or as a witness.

Mr. Hutt has been a member of the National Academy of Medicine (formerly called the Institute of Medicine (IOM)) of the National Academies of Science, Engineering, and Medicine (NASEM) since the IOM was formed in 1971. He has served on the IOM Executive Committee and other NAS and IOM committees. In the past few years he has served on eight NASEM report review committees. He served as a member of the Working Group on the Innovation in Drug Development and Evaluation for President Obama's Council of Advisors on Science and Technology (PCAST). He served on the NIH Advisory Committee to Review the Guidelines for Recombinant DNA Research, the National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS established by the President's Cancer Panel, the Science Review Subcommittee of the FDA Science Board to review the FDA science needs in order to perform its regulatory mission, and published a major analysis that resulted in Congress doubling FDA appropriations during 2008-2013. He also served on the Panel on the Administrative Restructuring of the National Institutes of Health and on the Working Group to Review Regulatory Activities Within the Division of AIDS of the National Institute of Allergy and Infectious Diseases. He is a member of the Board of Directors of the Institute of Health Policy Analysis, and a past member of the Board of the AERAS Global TB Vaccine Foundation, the Foundation for Biomedical Research, and the California Life Sciences Association (formerly called the California Healthcare Institute). He has served on a wide variety of other academic and scientific Advisory Boards.

He has advised and represented the national trade associations for the food, prescription drug, nonprescription drug, dietary supplement, and cosmetic industries, and both large and small companies spanning the entire scope of FDA's jurisdiction. He has served on the Advisory Board for leading venture capital firms (e.g., Polaris Partners, Kearny Venture Partners, Frazier Healthcare

Partners, New Leaf Venture Partners, Sprout Group) and on the Board of Directors for more than 30 healthcare biotechnology companies (e.g., American Sterilizer, Parexel, Cell Genesys, IDEC Pharmaceuticals, Vivus, Phase Forward, CV Therapeutics, Momenta Pharmaceuticals, Ista Pharmaceuticals, Xoma, LifeLine Screening, Concert Pharmaceuticals, Living Proof, YourBio (formerly Seventh Sense), DBV Technologies, Selecta Biosciences, Moderna Therapeutics, Seres Therapeutics, Axcella Health, Rubius Therapeutics, Evelo Biosciences, Kaleido Biosciences, Pendulum (formerly Whole Biome), Immunomedics, CoLabs International, and Holoclara). Mr. Hutt has also been a member of several biotechnology company advisory boards.

Mr. Hutt is a member of the Board of Directors of the Critical Path Institute (a public-private partnership between FDA and the pharmaceutical industry), and has served on the IOM Roundtable for the Development of Drugs and Vaccines Against AIDS, the Advisory Committee to the Director of the National Institutes of Health, the NAS Committee on Research Training in the Biomedical and Behavioral Sciences, the NIH Advisory Committee to Review the Guidelines for Recombinant DNA Research, the National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS established by the President's Cancer Panel of the National Cancer Institute at the request of President Bush, the Keck Graduate Institute of Applied Life Sciences (one of the Claremont Colleges), and five Office of Technology Assessment advisory panels. He was a member of the New Foods Panel of the White House Conference on Food, Nutrition and Health and authored the panel report. He has twice been a councilor of the Society for Risk Analysis and has served as Legal Counsel to the Society as well as the American College of Toxicology.

He was twice asked to become the Deputy Assistant Secretary for Health: in the Department of Health, Education, and Welfare in 1973 by Assistant Secretary Charles C. Edwards and in the Department of Health and Human Services in 1986 by Assistant Secretary Robert E. Windom. He declined both offers. In 2001, Mr. Hutt's name was informally forwarded by the Bush Administration to Senator Edward Kennedy, then the Chair of the Senate HELP Committee, for consideration as the Commissioner of Food and Drugs. Senator Kennedy blocked the nomination by refusing to hold a confirmation hearing, on the ground that he would never hold a hearing for that position for anyone who has advised and represented the regulated industry. In 2005, following Mark McClellan's and Lester Crawford's tenures as

FDA Commissioner, Mr. Hutt's name was again informally discussed for consideration as the Commissioner of Food and Drugs. Senator Kennedy was no longer Chair of the HELP Committee but he again succeeded in blocking any potential nomination by threatening an all-out opposition for the same reason. Mr. Hutt was also under consideration as FDA Commissioner by the Trump Administration. He was one of the three final candidates, but he was not selected.

During the 1960s, Mr. Hutt litigated pro bono cases on behalf of homeless alcoholics and drug addicts. He co-argued the only alcoholism case ever heard in the United States Supreme Court, *Powell v. Texas*, and then drafted the legislation that created the National Institute of Alcohol Abuse and Alcoholism and the National Institute of Drug Abuse. Based on this work, two-thirds of the States have repealed their statutes that had made public intoxication a criminal offense.

He was named by The Washingtonian magazine as one of Washington's 50 best lawyers (out of more than 40,000) and as one of Washington's 100 most influential people; by the National Law Journal as one the 40 best health care lawyers in the United States; and by Global Counsel as the best FDA regulatory specialist in Washington, DC. Business Week referred to Mr. Hutt in June 2003 as the "unofficial dean of Washington food and drug lawyers." In naming Mr. Hutt in September 2005 as one of the eleven best food and drug lawyers, the Legal Times also referred to him as "the dean of the food-and-drug bar." In April 2005, Mr. Hutt was presented the Distinguished Alumni Award by FDA. In May 2005, he was given the Lifetime Achievement Award for research advocacy by the Foundation for Biomedical Research, and in 2016 he was made a member of the LMG Life Sciences Hall of Fame. The 2017 Who's Who Legal: Life Sciences described Mr. Hutt as "the best guy in the business" and the 2017 Chambers USA called him "a legend." In 1994, he was elected a Fellow of the Society for Risk Analysis. In 2016 he was elected a Fellow of the Institute of Food Technologists and a member of Phi Tau Sigma, the Honor Society for Food Science and Technology.

COVINGTON

Food & Drug Law: Past, Present & Future

Celebrating Peter Barton Hutt's 20 Years (thus far) at HLS

Peter Barton Hutt has worked at the Washington, DC law firm of Covington & Burling, specializing in Food and Drug Law, for more than five decades. He has represented clients in administrative, legislative, executive, and judicial settings. He began his law practice with the firm in 1960 and is now Senior Counsel; between 1971 to 1975, he was Chief Counsel for the Food and Drug Administration. The Best Lawyers in America selected Mr. Hutt as the 2013 FDA Lawyer of the Year for Washington, DC. Since 1994, Mr. Hutt has taught Food and Drug Law during Winter Term at Harvard Law School, covering all aspects of government regulation of food and drugs from ancient times to present.

Introductions and Welcome
Martha Minow, *Dean, Harvard Law School*

Tributes to Professor Hutt
- I. Glenn Cohen, *Assistant Professor, Harvard Law School; Faculty Co-Director, Petrie-Flom Center*
- Theodore Ruger, *Professor of Law, Penn Law School*
- Lewis Grossman, *Professor of Law, American University Washington College of Law*

Reflections
Peter Barton Hutt

Questions and Discussion
Dean Minow and Audience

Thursday, January 17, 2013, 4:00 p.m.

Wasserstein Hall, Milstein West AB, Harvard Law School

Reception to follow

For questions, contact petrie-flom@law.harvard.edu, 617-496-4662

Co-sponsored by the Petrie Flom Center and the HLS Dean's Office