William B Schultz
December 2022

PUBLICATIONS, CONGRESSIONAL TESTIMONY AND AWARDS

Publications

1. The Myth of Swing Voting: An Analysis of Voting Patterns on the Supreme Court, 50 *N.Y.U. Law Review* 798 (1975) (coauthor).

2. Drug Marketing Today: A Consumer View, 33 *Food, Drug, Cosmetic L.J*. 614 (1978).

3. "An Industry Hiding From Liability," *The Washington Post* (April 28, 1979) (coauthor).

4. "Supreme Court Upholds Law Insulating Nuclear Industry from Liability for a Nuclear Accident," *Critical Mass Journal* (July 1979).

5. "Labels, Bans, and Consumer Preferences," *Banbury Report 6: Product Labeling and Health Risks* (Cold Spring Harbor Laboratory 1980).

6. "How the Government Made Nuclear Accident Victims Subsidize Nuclear Power," *Critical Mass Journal* (June 1980).

7. "A Lot of Baloney About Delaney," *Washington Post* (November 21, 1981).

8. "To Give Drug Industry Longer Patent Terms Is Just Aiding the Rich," *Newsday* (October 1, 1982).

9. "United States v. Generix: A Preview," 37 *Food, Drug, Cosmetic L.J.* 337 (1982).

10. "F.D.A.," *The New York Times* (February 3, 1983) (coauthor).

11. "Contrary Signals from the FDA," *U.S.A. Today Magazine* (January 1984) (coauthor).

12. Chapter: "Drugs," *Retreat from Safety* (Pantheon Books 1984).

13. "The Bitter AfterTaste of Saccharin," 40 *Food Drug, Cosmetic L.J.* 66 (Jan. 1985), reprinted in III Agriculture and Human Values 83 (1986).

14. "Public Interest Law with Bread on the Table," 71 *ABA Journal* 74 (Feb. 1985) (coauthor).

15. "Food Safety Laws Working Fine," *At Home with Consumers* (June 1985).

16. "The Dyes and the Laws," Letter to the Editor, *The Washington Post* (August 1, 1985) (coauthor).

16a. "Rebating. A Free Market Concept," *Best's Review* (August 1985)

17. "Public Citizen Fights for Initiatives in D.C.," *Public Citizen Magazine* (September 1985).

18. "Rent Control and the Post," Letter to the Editor, *The Washington Post* (November 24, 1985) (coauthor).

19. "Contamination Reexamination," Letter to the Editor, *The Wall Street Journal* (July 14, 1986).

20. "But Which Red Dye?," *The Washington Post* (February 27, 1987).

21. "Don't Put the Sick at Further Risk," *USA Today* (March 24, 1987).

22. *The Judicial Record of Judge Robert H. Bork* (August 1987) (co-author of book and director of project), reprinted at 9 *Cardoza L. Rev.* 297 (1987).

23. "An Obstacle to Public Safety," Health Magazine, *The Washington Post* (May 10, 1988) (coauthor).

24. "Why the FDA's De Minimis Interpretation of the Delaney Clause Is a Violation of Law," 7 *Journal of the American College of Toxicology* 521 (1988).

25. Letter to the Editor on De Minimis and the Delaney Clause, *The New England Journal of Medicine* (April 6, 1989).

26. "Ban Red Dye to Protect Our Health," *USA Today* (August 16, 1989).

27. "On Good Authority From Reader's Digest," *The Washington Post* (August 19, 1989).

28. Civil Enforcement, *America's Transition: Blueprints for the 1990s* (1989).

29. Food & Drug, *America's Transitions. Blueprints for the 1990s* (1989).

30. "Reforming the Civil Division of the Department of Justice," Changing America: Blueprints for the New Administration (1993) (coauthor).

31. "Food, Drugs and Medical Devices," *Changing America: Blueprints for the New Administration* (1993).

32. "We're Not Dragging Our Feet on New Drugs," *The Washington Post* (April 19, 1995).

33. "Some Thoughts on FDA Reform," *Tufts CSDD Newsletter*, Tufts Center for the Study of Drug Development, Vol. 21, No. 1 (February 1996).

34. "Should Drug Firms Be Allowed to Give Doctors Peer Reviewed Reprints on Off-Label Uses?" *Physicians Weekly*. Vol. 111, No. 12 (March 25, 1996).

35. "The Food and Drug Administration's Regulation of Tobacco Products," 355 *New Eng. J. Med* (1996) (co-author).

36. "The FDA's Decision to Regulate Tobacco Products," 18 *Pace L. Rev.* 27 (1997).

37. "Tort Law Deference to FDA Regulation of Medical Devices," *88 Georgetown L J.* 2119 (July 2000) (coauthor).

38. "The Leaderless F.D.A.," *The New York Times* (April 17, 2001).

39. "How to Improve Drug Safety," *The Washington Post*, December 2, 2004, A35.

40. "A Modest Servant of Law and Life," *The Washington Post*, November 18, 2005, A23.

41. "I Met the President Because of WordPerfect 6.1," *FDA: A Century of Consumer Protection* (Food and Drug Law Institute, 2006).

42. "Something's Rotten in Food Oversight," *The Washington Post*, September 24, 2006 (coauthor).

43. "No Right to an Experiment," *Legal Times*, September 10, 2007 (coauthor).

44. "Bolstering the FDA's Drug-Safety Authority," *The New England Journal of Medicine*, November 29, 2007.

45. "Generic Drugs: ANDAs, Section 505(b)(2) NDAs, Patents and Exclusivities," Chapter in *Food and Drug Law and Regulation* (Food and Drug Law Institute, 2008) (coauthor).

46. "Congress Should Establish a Tobacco Regulation Program at the Food and Drug Administration," *Cancer Prevention Research* (July 2008).

47. "A Hard Pill to Swallow: Barriers to Effective FDA Regulation of Nanotechnology-Based Dietary Supplements" (Wilson Center 2009) (coauthor).

48. "Trump's new FDA commissioner has a huge decision to make," *The Washington Post* (May 16, 2017), reprinted in *Chicago Tribune* (May 17, 2017).

49. "Maryland's price-gouging law targets the wrong prescription drugs," *The Washington Post*, August 4, 2017.

50. Don't enact a law that diminishes the incentive for generic companies to challenge patents, *The Hill* (March 20, 2019) (coauthor).

51. Should We Fast-Track a Vaccine for the Coronavirus?, *The New York Times* (September 17, 2020).

52. Who should get the COVID vaccine next? *USA Today* (December 13, 2020)

53. To Improve Competition in Generic Drug Markets, The FDA Should Discount User Fees For Small Players, *Health Affairs* (April 15, 2021) (coauthor)

54. An Evidence-Based Assessment of the Blocking Act, https://www.thefdalawblog.com/2022/05/a-new-report-takes-an-evidence-based-approach-to-analyzing-the-blocking-act/ (May 2022) (coauthor)

55. Transparency practices at the FDA: A barrier to global health, *Science* (August 2022) (coauthor)

Congressional Testimony

1. Senate Committee on Agriculture, Nutrition and Forestry, Safety of Nitrites and Their Status as Additives (September 15, 1978).

2. Senate Committee on Commerce, Science and Transportation, Compensation Provisions in Proposed Liquefied Energy Gases Legislation (December 12, 1978).

3. Senate Committee on Human Resources, Subcommittee on Health and Scientific Research, Food Safety Policy and Saccharin (May 9, 1979).

4. House Commerce Committee, Subcommittee Health and the Environment, Saccharin Moratorium (May 23, 1979).

5. House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, Over-the-Counter Drugs (June 22, 1979).

6. House Committee on Interior and Insular Affairs, Subcommittee on Energy and the Environment, The Price-Anderson Act (July 9, 1979).

7. House Committee on Interior and Insular Affairs, Subcommittee on Energy and the Environment, Reform of the Price Anderson Act (March 14, 1980).

8. House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, Competition in the Drug Industry (March 10, 1981).

9. House Committee on Energy and Commerce, Subcommittee on Health and the Environment, Patent Term Restoration Act of 1981 (April 1, 1981).

10. House Committee on Agriculture, National Science Council Act (June 24, 1981).

11. House Judiciary Committee, Subcommittee on Courts, Civil Liberties, and the Administration of Justice, on H.R. 1937, Patent Restoration Act of 1981 (November 12, 1981).

12. Senate Committee on Labor and Human Resources, Food Safety Laws (June 10, 1983).

13. House Committee on Energy and Commerce, Subcommittee on Health and the Environment, FDA Approval Labeling Act and Drug Price Competition Act of 1983 (July 25, 1983).

14. Senate Committee on the Judiciary, Patent-Term Extension (August 23, 1983).

15. House Committee on Energy and Commerce, Subcommittee on Health and the Environment, Drug Labeling and Advertising (October 3, 1983).

16. Senate Committee on Commerce, Subcommittee on Science, and Transportation, Surface Transportation, Legislation Relating to Automobile Odometer Tampering (April 12, 1984).

17. Senate Committee on Labor and Human Resources, Generic Drug Approval and Patent-Term Extension (June 28, 1984).

18. House Committee on the Judiciary, Subcommittee on Courts, Civil Liberties and the Administration of Justice, Patent Term Extension Legislation (October 8, 1987).

19. House Committee on Energy and Commerce, Subcommittee on Health and the Environment, RJR's Premier Cigarette (July 29, 1988).

20. House Committee on Post Office and Civil Service, Subcommittee on Civil Service, OMB Censorship of Federal Employees (May 17, 1989).

21. House Committee on Energy and Commerce, Subcommittee on Health and the Environment, Pesticide Legislation (May 31, 1989).

22. House Committee on Science Risk Assessment and Cost Benefit Analysis (January 31, February 3, 1995).

23. House Committee on Commerce, Risk Assessment and Cost/Benefit Analysis for New Regulation (February 1, 2, 1995).

24. House Committee on Commerce, Drugs and Biologics (May 25, 1995).

25. House Committee on Commerce, Food Quality Protection Act of 1995 (June 7, 29, 1995).

26. House Committee on Government Reform, Food and Drug Enforcement Standards for Medical Devices (September 14, 1995).

27. Senate Committee on Labor and Human Resources, More Information for Better Patient Care (February 22, 1996).

28. House Committee on Commerce, FDA Policy on Home Drug Testing Kits (February 6, 1997).

29. Senate Committee on Labor and Human Resources, The FDA's Performance, Efficiency, and Use of Resources (March 19, April 11, 1997).

30. Senate Committee on Labor and Human Resources, Tobacco Legislation (February 10, 1998).

31. House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies, Hearing on Agriculture, Rural Development, Food and Drug Administration, and Related Agency Appropriations (February 25, 1998).

32. Senate Committee on Government Affairs, Permanent Subcommittee on Investigations, Safety of Imported Foods (September 24, 1998).

33. House Committee on the Judiciary, Subcommittee on Commercial and Administrative Law, Federal Agency Nonacquiescence (September 16, 1999).

34. Senate Committee on the Judiciary, The Law of Biologic Medicine (June 23, 2004).

35. Senate Committee on Health, Education, Labor and Pensions, FDA's Drug Approval Process: Up to the Challenge (March 1, 2005).

36. Senate Commerce Committee, Interstate Commerce, Trade and Tourism Subcommittee, Policy Implications of Pharmaceutical Importation for US Consumers (March 7, 2009).

Awards/Recognitions

- *Chambers USA: America's Leading Lawyers for Business* (Washington, DC)
- *The Best Lawyers in America*, FDA Law
- *Super Lawyers* (Washington, DC)
- AV Peer Review Rated, *Martindale-Hubbell*
- 2020 Litigation Trailblazer, *The National Law Journal*
- 2019 *Law360* Health MVP of the Year
- 2017 FDA Distinguished Alumni Award
- 2006 100 Most Influential Lawyers in America, *The National Law Journal*
- 2010 Champion, Legal Times, *The National Law Journal*
- Top Lawyers, *Washingtonian*, 2004, 2007, 2009
- 2006, 100 Most Influential Lawyers, *The National Law Journal*
- 2005 Leading Lawyers: Top Food and Drug Attorneys, *Legal Times*

- 2005 Distinguished Service and Leadership Award, Food and Drug Law Institute
- 1997 National Public Affairs Special Recognition Award, American Heart Association
- Commissioner's Special Citation, Food and Drug Administration, 1995, 1997
- 1989 50 Under 50 (Lawyers to Watch Under 50), *The National Law Journal*