

## CURRICULUM VITAE

**Name:** Stephen M. Feinstone, M.D.

**Date and Place of Birth:** July 24, 1944; Greenwich, CT, U.S.A

**Citizenship:** United States

**Marital Status:** Married, one child

**Education:** June, 1966 B.A., Johns Hopkins University, Baltimore, MD  
Sept 1966- Dec 1969 M.D., University of Tennessee College of Medicine, Memphis, TN

**Brief Chronology of Employment:**

1968	3 months student Fellowship, Infectious Diseases, University of Tennessee, Memphis, Tennessee
Jan –June 1970	6 months: Fellowship in Infectious Diseases, College of Wisconsin, Milwaukee, Wisconsin
July1970 – June 1971	Internship, Medical College of Wisconsin, Milwaukee, Wisconsin
July 1971 – June 1974	Research Associate, PHS, National Institutes of Health, LID, NIAID, Bethesda, Maryland
July1974 – June 1976	Residency, Georgetown University Hospital, Washington, D. C. and Washington Veterans Administration Hospital (Internal Medicine)
July 1976 – May 1989	Senior Investigator, Laboratory of Infectious Diseases, NIAID, National Institutes of Health, Bethesda, Maryland
May 1989- Oct 2012	Chief, Laboratory of Hepatitis Viruses, Division of Viral Products, CBER/FDA

October 2012- Present      Adjunct Professor, Department of Biochemistry and  
Molecular Medicine, George Washington University  
School of Medicine

**Military Service:**

1971 – 1974                      USPHS  
1976 – 2004                      USPHS, Rank, Captain (06)

**Societies:**

American Society for Microbiology  
Infectious Diseases Society of America (Fellow)  
American Society for Virology  
American Association for the Study of Liver Diseases  
American Association for the Advancement of Science (Fellow)

**Honors and Other Specific Recognition:**

Recipient, PHS Commendation Medal X 2,  
PHS Unit Commendation  
Diplomat: American Board of Internal Medicine, 1976  
Dept. of Commerce, Inventors Incentive Award 1984  
Honorary Professor, Zhezhiang Institute of Hygiene, Hangzhou,  
China, 1985  
Special Honoree, Eighth Triennial International Symposium on Viral  
Hepatitis and Liver Disease, Tokyo, 1993  
Visiting Professor, Kanazawa University School of Medicine, 1999  
Elected Fellow of The American Association for the Advancement of  
Science, , 2003  
PHS Distinguished Service Medal, 2003

**Research Interest:**      Infectious diseases and vaccines, virology, viral vaccines, viral  
hepatitis

**Recent Scientific Recognition (partial list):**

Invited Participant and Special Recognition Honoree, 8<sup>th</sup> Triennial International  
Symposium on Viral Hepatitis and Liver Disease, Tokyo, Japan, May, 1993.

Invited Participant, Eighth Annual International Symposium on Hepatitis C and  
Related Viruses, Gold Coast, Australia, August, 1995.

Invited participant, IX Triennial International Symposium of Viral  
Hepatitis and Liver Diseases,      Rome Italy, April 6, 1996.

Invited speaker X Triennial International Symposium of Viral Hepatitis and Liver Diseases, Atlanta, GA May, 2000. Delivered the plenary lecture on Hepatitis C Vaccines

Invited Participant, Eighth Annual International Symposium on Hepatitis C and Related Viruses, Gold Coast, Australia, Dec., 2000

Invited Participant (Meet the Professor) Annual Meeting American Association for the Study of Liver Disease, Nov. 2000 and 2001

Invited Participant American Association on the Study of Liver Disease single topic conference on New Approaches to Hepatitis C Therapy, 2001

Invited Participant 8<sup>th</sup> International Symposium on Hepatitis C Virus and Related Viruses, Paris France, September 2001

Member of Editorial Board and/or Reviewer for the Following Journals:

*Hepatology*: **Associate Editor, 1999-2001**

*Journal of Infectious Diseases*

*Journal of Virology*

*Journal of Viral Hepatitis*: **Editorial Board**

*The New England Journal of Medicine*

#### **U.S. Patents:**

1. INACTIVATION OF A LIPID VIRUS  
U.S. Patent #: 4,511,556  
Inventors: Robert H. Purcell and Stephen M. Feinstone
2. ISOLATION OF HEPATITIS A VIRUS STRAIN HM-175  
U.S. Patent #: 4,532,215  
Inventors: Richard J. Daemer, Robert H. Purcell, Stephen M. Feinstone and Ian D. Gust
3. VACCINE AGAINST HEPATITIS A VIRUS  
U.S. Patent #: 4,894,228  
Inventors: Robert H. Purcell, John R. Ticehurst, Jeffrey I. Cohen, Suzanne U. Emerson, Stephen M. Feinstone and Ian D. Gust
4. INACTIVATION OF VIRUSES CONTAINING ESSENTIAL LIPIDS  
U.S. Patent #: 4,581,31

Inventors: Robert H. Purcell and Stephen M. Feinstone

5. ISOLATION OF HEPATITIS A VIRUS STRAIN HM-175

U.S. Patent #: 4,636,469

Inventors: Richard Daemer, Stephen M. Feinstone, Ian D. Gust and Robert H. Purcell

6. TECHNIQUES FOR PRODUCING SITE DIRECTED MUTAGENESIS OF CLONED DNA

U.S. Patent #:

Inventors: Stephen M. Feinstone, Czeslaw Wychowski, Jonathan Silver and Suzanne U. Emmerson

7. CDNA ENCODING ATTENUATED CELL CULTURE ADAPTED HEPATITIS A VIRUS GENOME

U.S. Patent #: 5,478,746

Inventors: Jeffrey I. Cohen, Robert H. Purcell, Stephen M. Feinstone and John R. Ticehurst

8. RECOMBINANT DNA ENCODING HEPATITIS A VIRUS RECEPTOR

U.S. Patent # 5,622,861

Inventors: Gerardo Kaplan and Stephen M. Feinstone

9. MODIFIED HCV PEPTIDE VACCINES

U.S. Patent # 7,074,410

Inventors: Jay A. Berzofsky, Stephen M. Feinstone and Marian E. Major

**Regulatory Experience:**

- Responsible for all hepatitis vaccine submissions to the Center for Biologic Evaluation and Research (CBER)/FDA including IND and BLA submissions. Also responsible for all vaccine submissions for rotavirus, noroviruses and SARS coronavirus.
- Chaired multiple licensing committees for new vaccines as well as supplemental BLA submissions for existing vaccines.
- Serve frequently as a consultant on hepatitis issues for non-vaccine related applications in the areas of blood and plasma products, biologic therapeutics, drugs and diagnostics.
- Consultant with international regulatory agencies (EMEA) and WHO on viral hepatitis issues

**PUBLICATIONS**

1. Feinstone S M., Beachey, E.H., and Rytel, M.W. Induction of delayed hypersensitivity to influenza and mumps viruses in mice. J. Immunol. 103:844-849, 1969.
2. Alter, H.J., Holland, P.V., Purcell, R.H., Lander, J.J., Feinstone, S.M., Morrow, A.G., and Schmidt, P.J. Post-transfusion hepatitis after exclusion of commercial and hepatitis after

- exclusion of commercial and hepatitis B antigen-positive donors. Ann. Intern. Med. 77:691-699, 1972.
3. Feinstone, S.M., Hensley, G.T., and Rytel, M.W. Post-coxsackie virus B3 myocardiopathy in mice. Proc. Soc. Exp. Biol. Med. 1444:345-350, 1973.
  4. Feinstone, S.M., Purcell, R.H., and Kapikian, A.Z. Hepatitis A: detection by immune electronmicroscopy of a virus-like antigen associated with acute illness. Science 182:1026-1028, 1973.
  5. Feinstone, S.M., Kapikian, A.Z., Gerin, J.L., and Purcell, R.H. Buoyant density of the hepatitis A virus-like particle in cesium chloride. J. Virol. 13:1412-1414, 1974.
  6. Alter, H.J., Purcell, R.H., Holland, P.V., Feinstone, S.M., Morrow, A.G., and Moritsugu, Y. Clinical and serological analysis of transfusion-associated hepatitis. Lancet ii:838-841, 1975.
  7. Dienstag, J.L., Feinstone, S.M., Kapikian, A.Z., and Purcell, R.H.: Immune electron microscopy and hepatitis A. Lancet i:102, 1975.
  8. Dienstag, J.L., Feinstone, S.M., Kapikian, A.Z., Purcell, R.H., Boggs, J.D., and Conrad, M.E. Fecal shedding of hepatitis A antigen. Lancet ii:765-767, 1975.
  9. Dienstag, J.L., Feinstone, S.M., Purcell, R.H., Hoofnagle, J.H., Barker, L.F., London, W.T., Popper, H., Peterson, J.M., and Kapikian, A.Z. Experimental infection of chimpanzees with hepatitis A virus. J. Infect. Dis. 132:532-545, 1975.
  10. Feinstone, S.M., Kapikian, A.Z., Purcell, R.H., Alter, H.J., and Holland, P.V. Transfusion-associated hepatitis not due to viral hepatitis type A or B. N. Engl. J. Med. 292:767-770, 1975.
  11. Kapikian, A.Z., Feinstone, S.M., Purcell, R.H., Wyatt, R.G., Thornhill, T.S., Kalica, A.R., and Chanock, R.M. Detection and identification by immune electronmicroscopy of fastidious agents associated with respiratory illness, acute non-bacterial gastroenteritis and hepatitis A. In Perspectives in Virology IX, Chapter 2, 1975, pp. 9-47.
  12. Maynard, J.E., Lorenz, A.D., Bradley, D.W., Feinstone, S.M., Krushak, D.H., Barker, L.F., and Purcell, R.H. Review of infectivity studies in non-human primates with virus-like particles associated with MS-1 hepatitis A. Am. J. Med. Sci. 270:85, 1975.
  13. Purcell, R.H., Dienstag, J.L., Feinstone, S.M., and Kapikian, A.Z. Relationship of hepatitis A antigen to viral hepatitis. Am J. Med. Sci. 270:61-71, 1975.
  14. Purcell, R.H., Feinstone, S.M., and Kapikian, A.Z. Recent advances in hepatitis A research. In Greenwalt, T.J. and Jamieson, G.A. (eds.): Transmissible Disease and Blood Transfusion. New York, Grune & Stratton, Inc., 1975, pp. 11-26.

15. Sever, J.L., Kapikian, A.Z., Feinstone, S.M., Purcell, R.H., and Gilkeson, M.R. Hepatitis A and Down's Syndrome: lack of an association. J. Infect. Dis. 134:198-200, 1976.
16. Barker, L.R., Dienstag, J.L., Lorenz, D.E., Purcell, R.H., Wong, D.C., Feinstone, S.M., Peterson, M.R., and Rosen, M.W. Serological and animal inoculation studies of a communal outbreak of viral hepatitis, type A. Am. J. Med. Sci. 274:247-253, 1977.
17. Dienstag, J.L., Feinstone, S.M., Purcell, R.H., Wong, D.C., Alter, H.J., and Holland, P.V. Non-A, non-B post-transfusion hepatitis. Lancet i:560-562, 1977.
18. Hoofnagle, J.H., Gerety, R.J., Tabor, E., Feinstone, S.M., Barker, L.F., and Purcell, R.H. Transmission of non-A, non-B hepatitis. Ann. Intern. Med. 87:14-20, 1977.
19. Mathiesen, L.R., Feinstone, S.M., Purcell, R.H., and Wagner, J.A. Detection of hepatitis A virus by immunofluorescence. Infect. Immun. 18:524-530.
20. Moseley, J.W., Redeker, A.G., Feinstone, S.M., and Purcell, R.H. Multiple hepatitis viruses in multiple attacks of acute viral hepatitis. N. Engl. J. Med. 296:75-78, 1977.
21. Alter, H.J., Purcell, R.H., Feinstone, S.M., Holland, P.V., and Morrow, A.G. Non-A, non-B hepatitis: review and interim report of ongoing prospective study. In Vyas, G.N., Cohen, S.N., Schmid, R. (eds.): Viral Hepatitis. Philadelphia, Pa., Franklin Institute Press, 1978, pp. 359-3170.
22. Feinstone, S.M., Moritsugu, Y., Shih, J.W.K., Gerin, J.L., and Purcell, R.H. Characterization of hepatitis A virus. Proceedings of the Faculty of the Second U.C.S.F. Symposium on Viral Hepatitis. 1978.
23. Feinstone, S.M., Purcell, R.H. Non-A, non-B hepatitis. Ann. Rev. Med. 29:359-366, 1978.
24. Feinstone, S.M., Purcell, R.H., and Barker, L.F. Viral Hepatitis. In Lennette, E.H., and Schmidt, N.J. (eds.): Diagnostic Procedures for Viral and Rickettsial Infections. New York, American Public Health Association, 1978.
25. Mathiesen, L.R., Feinstone, S.M., and Purcell, R.H. Present methods for detection of hepatitis A antigen and antibody. Acta Pathol. Microbiol. Immunol. Scand. 1978.
26. Mathiesen, L.R., Feinstone, S.M., Wong, D.C., Skinhoj, P., and Purcell, R.H. Enzyme-linked immunosorbent assay for detection of hepatitis A antigen in stool and antibody to hepatitis A antigen in sera: comparison with solid-phase radioimmunoassay, immune electron microscopy, and immune adherence hemagglutination assay. J. Clin. Microbiol. 7:184-193.
27. Purcell, R.H., Feinstone, S.M., Wong, D.C., Alter, H.J. Detection of a novel antigen in two cases of non-A, non-B hepatitis, a recently recognized persistent infection of

- probable viral origin. Proc. of the 1978 ICN-UCLA Symposium on Persistent Viruses, 1978, pp. 538-549.
28. Shimizu, Y.K., Mathiesen, L.R., Lorenz, D., Drucker, J., Feinstone, S.M., Wagner, J.A., and Purcell, R.H. Localization of hepatitis A antigen in liver tissue by peroxidase-conjugated antibody method: light and electronmicroscopy studies. J. Immunol. 121:1671-1679, 1978.
  29. Dienstag, J.L., Bhan, A.K., Alter, H.J., Feinstone, S.M., and Purcell, R.H. Circulating immune complexes in non-A, non-B hepatitis. Lancet i:1265-1267, 1979.
  30. Shimizu, Y.K., Feinstone, S.M., Purcell, R.H., Alter, H.J., London, W.T. Non-a, non-B hepatitis: ultrastructural evidence for two agents in experimentally infected chimpanzees. Science 205:197-200, 1979.
  31. Daemer, R.J., Feinstone, S.M., Alexander, J.J., Tully, J.G., London, W.T., Wong, D.C., and Purcell, R.H. PLC/PRF/5 (Alexander) hepatoma cell line: further characterization and studies of infectivity. Infect. Immun. 30(2):607-611, 1980.
  32. Feinstone, S.M. and Purcell, R.H. New methods for the serodiagnosis of hepatitis A. Gastroenterology 78:1092, 1980. [Editorial]
  33. Gust, I.D., Feinstone, S.M., Purcell, R.H., Alter, H.J. Detection of antibodies to single-stranded DNA in naturally acquired and experimentally induced viral hepatitis. J. Med. Virol. 6:1-10, 1980.
  34. Mathiesen, L.R., Moller, A.M., Purcell, R.H., London, W.T., and Feinstone, S.M. Hepatitis A virus in the liver and intestine of marmosets after oral inoculation. Infect. Immun. 28:45-48, 1980.
  35. Popper, H., Dienstag, J.L., Feinstone, S.M., Alter, H.J., Purcell, R.H. The pathology of viral hepatitis in chimpanzees. Virchows Arch. [A] 387:91-96, 1980.
  36. Popper, H., Dienstag, J.L., Feinstone, S.M., Alter, H.J., and Purcell, R.H. Lessons from the pathology of viral hepatitis in chimpanzees. In Bianchi, L., Gerok, W., Sickinger, K., and Stadler, G.A. (eds.): Virus and the Liver. Lancaster, MTP Press, 1980, pp. 137-150.
  37. Daemer, R.J., Feinstone, S.M., Gust, I.D., and Purcell, R.H. Propagation of human hepatitis A virus in African green monkey kidney cell culture: primary isolation and serial passage. Infect. Immun. 32:388-393, 1981.
  38. Feinstone, S.M., Alter, H.J., Dienes, H.P., Shimizu, Y., Popper, H., Blackmore, D., Sly, D.L., London, W.T., and Purcell, R.H. Non-A, non-B hepatitis in chimpanzees and marmosets. J. Infect. Dis. 144:588-594, 1981.
  39. Hansson, B.G., Calhoun, J.K., Wong, D.C., Feinstone, S.M., Purcell, R.H., Pannuti, C.S., Pereira, J.L., Koff, R.S., Dienstag, J.L., and Iwarson, S. Serodiagnosis of viral hepatitis A by a solid-phase radioimmunoassay specific for IgM antibodies. Scand. J. Infect. Dis. 13:5-9, 1981.

40. Hoofnagel, J.H. and Feinstone, S.M. Serological tests for non-A, non-B hepatitis: controversy. Liver 1:177-182, 1981.
41. Feinstone, S.M., Alter, H.J., Dienes, H.P., and Purcell, R.H. Studies on non-A, non-B hepatitis in chimpanzees and marmosets. In Szmuness, W., Alter, H.J., and Maynard, J.E. (eds.): Viral Hepatitis: International Symposium. Philadelphia, Pa., the Franklin Institute Press, 1982, pp. 295-304.
42. Feinstone, S.M., Daemer, R.J., Gust, I.D., and Purcell, R.H. Live attenuated vaccine for hepatitis A. Dev. Biol. Stand. 54:429-432, 1983.
43. Feinstone, S.M., Mihalik, K.B., Kamimura, T., Alter, H.J., London, W.T., and Purcell, R.H. Inactivation of hepatitis B virus and non-A, non-B hepatitis by chloroform. Infect. Immun. 41:816-821, 1983.
44. Feinstone, S.M. and Purcell, R.H. Evidence for non-A, non-B viruses. International Symposium on Viral Hepatitis, Turin, Italy, 1983. In Verme, G., Bonino, F., Rizzetto, M. (eds.): Delta Infection and viral hepatitis. New York, Alan R. Liss, 1983, pp. 29-39.
45. Gust, I.D., Coulepis, A.G., Feinstone, S.M., Locarnini, S.A., Moritsugu, Y., Najera, R., Siegl, G. Taxonomic classification of hepatitis A virus. Intervirology 20:1-7, 1983.
46. Kamimura, T., Ponzetto, A., Bonino, F., Feinstone, S.M., Gerin, J.L., and Purcell, R.H. Cytoplasmic tubular structures in liver of HBsAg carrier chimpanzees infected with delta agent and comparison with cytoplasmic structures in non-A, non-B hepatitis. Hepatology 3(5):631-637, 1983.
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48. Feinstone, S.M. Non-A, non-B hepatitis. In Belshe, B. (ed): Textbook of Human Virology. Littleton, Massachusetts, PSG Publishing Co., 1984, pp. 757-777.
49. Feinstone, S.M., Hoofnagle, J.H. Non-A, maybe-B hepatitis. N. Engl. J. Med. 311:185-189.
50. Baroudy, B.M., Ticehurst, J.R., Miele, T.A., Maizel, J.V., Purcell, R.H., and Feinstone, S.M. Sequence analysis of the hepatitis A virus cDNA coding for the capsid to vaccine development. In Lerner, R., Brown, F., and Chanock R.M. (eds.): Vaccines 85: Modern Approaches to Vaccines: Molecular and Chemical Basis of Resistance to Viral,



Bacterial, and Parasitic Diseases. New York, Cold Spring Harbor Laboratory , 1985, pp. 249-254.

51. Purcell, R.H., Feinstone, S.M., Daemer, R.J., Ticehurst, J.R., and Baroudy, B.M. Approaches to the development of hepatitis-A vaccines: the old and the new. In Chanock, R.M. and Lerner, R.A. (eds.): Vaccines 85: Modern Approaches to Vaccines: Molecular and Chemical Basis of Virus Virulence and Immunogenicity. New York, Cold Spring Harbor Laboratory, 1984, pp. 59-63.
52. Purcell, R.H., Feinstone, S.M., Ticehurst, J.R., Daemer, R.J., and Baroudy, B.M. Hepatitis A virus. In Vyas, G.N., Dienstag, J., Hoofnagle, J. (eds.): Viral Hepatitis and Liver Disease. Orlando, Florida, Grune & Stratton, 1984, pp. 9-22.
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57. Tassopoulos, N.C., Papaevangelou, G.J., Roumeliotou-Karayannis, A., Ticehurst, J.R., Feinstone, S.M., and Purcell, R.H. Search for hepatitis B virus DNA in sera from patients with acute type B or non-A, non-B hepatitis. J. Hepatol. 2:410-418.
58. Quinnan, G.V., Jr., Wells, M.A., Wittek, A.E., Phelan, M.A., Mayner, R.E., Feinstone, S., Purcell, R.H., and Epstein, J.S. Inactivation of human T lymphotropic virus, type III (HTLV-III) by heat, chemicals, and irradiation. Transfusion 26:481-483, 1986.
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60. Shimizu, Y., Purcell, R.H., Gerin, J.L., Feinstone, S.M., Ono, Y., Shikata, T. Further studies by immunofluorescence of the monoclonal antibodies associated with experimental non-A, non-B hepatitis in chimpanzees and their relation to D hepatitis. Hepatology 6:1329-1333, 1986.
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62. Feinstone, S.M. Hepatitis A virus. In Ostrow, J.D. et al. (eds.): Hepatology Update -- Portal Hypertension; Viral Hepatitis. (Syllabus for AASLD Postgraduate Course on Viral Hepatitis, November 2, 1986). Thorofare, N.J., Charles B. Slack, Inc., 1987, pp. 139-156.
63. Cohen, J.I., Rosenblum, B., Ticehurst, J.R., Daemer, R., Feinstone, S., and Purcell, R.H. Complete nucleotide sequence of an attenuated hepatitis A virus: comparison with wild-type virus. Proc. Natl. Acad. Sci. USA 84:2497-2501, 1987.
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66. Ticehurst, J.R., Feinstone, S.M., Chestnut, T., Tassopoulos, N., Popper, H., and Purcell, R.H. Detection of hepatitis A virus by extraction of viral RNA and molecular hybridization. J. Clin. Microbiol. 25:1822-1829, 1987.
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68. Cohen, J.I., Ticehurst, J.R., Feinstone, S., Rosenblum, B., and Purcell, R.H. Hepatitis A virus cDNA and its RNA transcripts are infectious in cell culture. J. Virol. 61:3035-3039, 1987.

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76. Feinstone, S.M. and Gust, I. Modern concepts of hepatitis A. In Gitnick, G. (ed.): *Modern Concepts of Acute and Chronic Hepatitis*. New York, Plenum Publishing Corp., 1989, pp. 67-86.
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Recent Chapters:

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