Roger J. Porter, M.D.
Pharmaceutical Industry Experience at
Wyeth Research, 1992-2002

1. **June, 1992 to January, 1998: Vice President, Clinical Pharmacology:**
   - Arrived from the NIH and assumed responsibility for three disparate groups: Clinical Pharmacology Radnor, Clinical Pharmacokinetics and the Clinical Pharmacology Unit. Forged these 40 people into a highly functional Clinical Pharmacology team within four months. Created team in Paris for European studies. Expanded the group to 65-70 with the Lederle merger and globalization; overall team conducts 45-55 studies per year either at the CPU or by contract. Built a new 36-bed CPU in South Philadelphia.
   - Participated actively in a number of committees, especially Discovery Council, (took an active part in the evaluation of preclinical compounds), and the Research Operations Committee (was directly responsible for the clinical pharmacology programs for all compounds, and participated actively in the Phase II-III decisions for the same compounds).
     Personally in-licensed two potential antiepileptic compounds; participated in the entire process from start to finish. One drug dropped in Phase I; the second, retigabine, developed (largely under RJP's direction) through Phase IIB. Retigabine demonstrated a dose response curve and a highly significant difference from placebo, but was returned to Viatris (formerly Asta Medica) for portfolio reasons. Now owned jointly by Valeant and Glaxo-Smith-Kline and marketed (limited by adverse events).
   - Worked directly on the following compounds:
     - Effexor (venlafaxine)—antidepressant, NDA approved 1994
     - Ativan (lorazepam)---sNDA for status epileptics approved 1994
     - Prempro/Premphase (Premarin+MPA)---HRT approved 1994
     - Normiflo (ardeheparin)—Low MW Heparin-- NDA approved 1996
     - Effexor XR--(venlafaxine)--long-acting version--NDA approved 1997
     - Verdia (tasosartan)---angiotensin II antagonist---dropped
     - Totelle (trimegestone and 17B)—novel progestin for HRT—approved in 17 countries
     - Sonata (zaleplon)--non-benzo sleeping aid—approved 1998
     - minalrestat --aldose reductase inhibitor for complications of diabetes—outlicense candidate
     - Rapamycin (rapamune)---mTOR inhibitor for immunosuppression—approved, many filings
     - Duract (bromfenac)—NSAID analgesic—approved 1997, withdrawn
     - Alesse (levo-EE, 100/20)—oral contraception—NDA approved 1997
     - Minesse (gestodene)---novel progestin—approved internationally, not US
     - Protonix (pantoprazole)—oral and iv proton pump inhibitor for erosive esophagitis; NDA's approved 2000 and 2001, respectively
     - Fiblast (basic fibroblast growth factor)--stroke; dropped after Phase II
     - VPA-985--vasopressin antagonist--pure aquaretic—out-licensed
   - Retigabine---K+ channel blocker---epilepsy—see above

2. **January, 1998 to January 2000: Vice President, Clinical Research**
    - Assumed a radically changed position in early 1998. In the process of globalization of CR&D, assigned (in addition to Clin Pharm) the therapeutic areas of CNS, Cardiovascular and Metabolic Disorders—approximately ½ of the CR&D portfolio. Supervised the therapeutic area directors (all three of whom were relatively inexperienced; two were located in Europe). Had hands-on management of day-to-day issues in the Phase II-III development of new drugs (see below) in these areas. Handled globalization (the major concern of upper management), with therapeutic area leaders on both sides of the Atlantic; as a result of effective management, globalization became a non-issue.

    - In Metabolic Diseases, supervised the major late stage drug, Protonix (pantoprazole):
        - Oral NDA for acute gastro-esophageal reflux disease (GERD) approved in 2000
        - IV NDA for acute GERD approved in 2001
        - Oral sNDA for maintenance of GERD control approved in 2001
        - IV sNDA for Zollinger-Ellison syndrome approved in 2001
        - Oral SNDA for Zollinger-Ellison syndrome approved in 2001
    - In Cardiovascular Diseases, supervised the development of the following compounds:
        - RPSGL-IG, a p-selectin inhibitor, carried through Phase II
        - Aqueous Cordarone (amiodarone) (mixed action for arrhythmias) IV, dropped
        - Enbrel (soluble TNF receptor) investigated in two large studies of CHF
    - In CNS, supervised two late stage compounds:
        - Effexor XR (venlafaxine XR) sNDA approved for short-term generalized anxiety disorder (GAD) in March, 1999.
        - Effexor XR sNDA approved for long-term GAD in July, 2000; Ex-US approvals totaled 36 by May, 2000.
        - Effexor XR sNDA approved for depression with associated anxiety in 1999.
        - Effexor XR approved for rapid onset of action, Europe, 1999-2000
        - Effexor XR approved for relapse and recurrence of depression; sNDA approved 2001; European approvals 2000-2001
        - Sonata (zaleplon) NDA approved December, 1998; EMEA approved November, 1998
        - Sonata sNDA for 35-night sleep efficacy approved 2000
    - Work on the compounds mentioned in #1 above also continued, especially in Clinical Pharmacology

3. **January, 2000 to November, 2002: Vice President and Deputy Head, CR&D**
    - Once again, assumed a new job position. Therapeutic areas of CNS, Cardiovascular Diseases, and Metabolic Diseases returned to new Sr VP of CR&D. Provided direct administrative assistance (personnel, space, budget, etc) to the Sr. VP on all administrative matters. In addition, assignment now broadened to include the following:
        - Clinical Pharmacology (until Fall of 2001, when new dept. head hired by me)
            - Cited in October, 2001 by the Sr VP, CR&D, as the best Clin Pharm department in the industry

- Clinical Planning (until April, 2002, when group turned over to new VP of Clinical Operations)
  - Expanded into Clinical Operations; built telephone randomization system with global 24/7 help desk.
- Global Health Outcomes Assessment (until April, 2002, when group moved to Global Safety Surveillance and Epidemiology Department).
  - Provided a series of papers and positions to support late stage and marketed products
- Clinical Planning in Cambridge (to November, 2002)
  - Chaired "Cambridge Integration Committee" to assure harmonization when Genetics Institute CR&D merged with Wyeth CR&D
- All of ex-US CR&D : Canada, Europe, Latin America, Asia/Pacific (excluding Japan)
  - Assured a smooth transition in Canada from out-going to in-coming CR&D regional director
  - Chose the new head of CR&D for Europe; built a highly responsive team covering all of Western and Eastern Europe, Russia, South Africa, etc.
  - Personally initiated the first Wyeth CR&D trial in China at the Peking Union Hospital (also, incidentally, lectured there in both 1986 and in 1999)
  - Built an Asia/Pacific CR&D program in China and Taiwan, with permanent employees in both locations; made plans for Korea
  - Personally created the first CR&D department in Latin America. Headquartered in Sao Paolo, Brazil, this team initiated clinical studies in Brazil, Argentina, Chile, Peru, Venezuela, Costa Rica and Mexico.

4. Other Accomplishments:

- Co-chaired the Clinical Research Committee in CR&D that is responsible for reviewing all Worldwide Clinical Development Programs and all clinical protocols.
- Personally closed a clinical site in Munich
- Gave lectures on the Wyeth pipeline to a series of major managed care/large purchasers of Wyeth products. In demand right up to my retirement in November, 2002. Lecture adapted for the medical science liaisons in Global Medical Affairs.
- Frequently acted in the absence of the Sr.VP, CR&D, to run various meetings.
- Personally delivered the scientific report on the Phase II results of retigabine at a large epilepsy meeting in Europe.
- Very active in PhRMA. Past-Chair of the Clinical Pharmacology Committee, and Past-Chair of the Clinical Leadership Committee (tenure ended December, 2002).
- Provided numerous academic contacts for my colleagues at Wyeth, in part by maintaining my positions as Adjunct Professor of Neurology at the University of Pennsylvania and Adjunct Professor of Pharmacology at the Uniformed Services University of the Health Sciences.
- Member, U.S. Pharmacopeial Convention, Neurology Advisory Panel, 1995-2005