HOUSE COMMITTEE ON HEALTH AND HUMAN SERVICES

March 26, 2003 Hearing Room D
8:30 A.M. Tapes 65 – 68

MEMBERS PRESENT: **Rep. Jeff Kruse, Chair**
Rep. Billy Dalto, Vice-Chair
Rep. Carolyn Tomei, Vice-Chair
Rep. Gordon Anderson
Rep. Jeff Barker
Rep. Laurie Monnes Anderson
Rep. Ben Westlund

STAFF PRESENT: **Sandy Thiele-Cirka, Committee Administrator**
Mara McGraw, Committee Assistant

ISSUES HEARD: **Informational Meeting**
Pharmaceutical Development

- **John Swen, Global Research and Development, Pfizer, Inc.** ***From Molecule to Market***
- **Russ Spencer, Pfizer, Inc.**

These minutes are in compliance with Senate and House Rules. Only text enclosed in quotation marks reports a speaker's exact words. For complete contents, please refer to the tapes.

TAPE/#	Speaker	Comments
TAPE 65, A		
005	Chair Kruse	Calls meeting to order at 8:50 A.M. and opens informational meeting.
INFORMATIONAL MEETING		
022	Russ Spencer	Pfizer, Inc. Notes presentation represents Pharmaceutical Research Manufacturers of America (PhRMA) as a whole.
035	John Swen	Senior Director, U.S. Science and Policy, Global Research and Development, Pfizer, Inc. Presents power point on prescription drugs: *Molecule to Medicine* **(EXHIBIT A)**. Relates complexity of creating products for diverse environments, individuals and markets.
098	Rep. Westlund	Inquires on regulations for international production and marketing.
104	Rep. Dalto	Inquires on similarity of markets within the world wide market and questions top selling drugs.
107	Swen	Explains issues related to regulatory and patent process.
130	Rep. Dalto	Questions if drugs have the same composition in each country.
133	Swen	Responds affirmatively. Notes price of prescriptions relates to clinical and research guarantees. States more revenue generates more research in turn generating more products. Continues presentation.
173	Rep. Tomei	Questions the current assault on prescription drug companies.
174	Swen	Explains impact of media and criticism on development of medicines and drug companies. Addresses marketing budget compared to the research and development budget.
269	Rep. Tomei	Inquires on patent timeline.
270	Swen	Reports 17 years in United States. Explains that 10-12 years are spent in development.

277	Rep. Westlund	Inquires on percentage of marketing to research and development.
281	Swen	Reports 30-40% of budget is directed at marketing. Discusses the complexity of drug development as it relates to costs.
313	Rep. Dalto	Questions scientists' compensation.
315	Swen	Explains compensation is competitive with general scientific market. Discusses research process relating to diseases and cures. Notes role of National Institute of Health (NIH) is training not development. Reports private companies file 95 percent of patents.
382	Rep. Anderson	Questions Pfizer's hiring from NIH.
383	Swen	Reports Pfizer hires primarily from NIH.
392	Rep. Monnes Anderson	Inquires on collaborations with universities.
407	Swen	Discusses research collaboration with labs world wide.
450	Rep. Tomei	Inquires on benefit to lab when Pfizer develops drug.
TAPE 66, A		
015	Swen	Explains research and financial benefits to universities and labs. Details several phases of drug development.
095	Rep. Dalto	Questions Phase II studies.
097	Swen	Explains Phase II research studies are performed with healthy adults.
197	Chair Kruse	Inquires on Phase III studies relating to genome mapping.
202	Swen	Defers answer until later in presentation. Continues presentation on drug development, development timelines and patent process.
222	Rep. Dalto	Requests information on negotiation of reimbursement rates in Europe.
228	Swen	Elaborates on drug development and reimbursement process in Europe and impact on European research and development labs.
252	Rep. Dalto	Clarifies dictation of cost in Europe negatively impacted European drug research.
246	Swen	Concurs.
257	Rep. Anderson	Questions the patent extension process.
261	Swen	Explains patent of control release formulation and impact on patent timeline. Details the patent process guidelines.
302	Rep. Tomei	Questions the number of patents extensions.
304	Swen	Offers to present information at later date. Continues presentation on drug development, price controls and patents as they relate to replication by other manufacturers.
378	Rep. Dalto	Inquires on timeline of drug to market in regard to patents.
383	Swen	Explains regulatory timeline and process. Discusses capitol investments on drugs brought to market. Notes brand drugs subsidize development of other drugs in pharmacopoeia.
445	Rep. Tomei	Questions if data presented is current.
448	Swen	Notes new study recently completed. Offers updated data in capital returns.
TAPR 65, B		
037	Rep. Monnes Anderson	Inquires on pricing drugs out of business.
043	Swen	Comments on patient access programs offered by Pfizer. States the problem is coverage not cost. Speaks to maintaining brand companies to support research and development which supports generic industry. Explains that generic companies do not have the profit to support research and development.

132	Chair Kruse	Questions the impact of tort on mergers.
133	Swen	Speaks to drive toward mergers.
180	Rep. Dalto	Comments on the filter of data application.
183	Swen	Responds and explains that small companies are commercially validated. Notes that small molecule companies as compared to biotechnology companies. Explains the scale of clinical and regulatory infrastructure required to generate profit.
241	Rep. Monnes Anderson	Speaks to consolidation issues.
246	Swen	Notes natural consolidation. Identifies pressures that drive consolidation.
262	Rep. Tomei	Inquires on number of manufacturers belonging to PhRMA.
263	Swen	Estimates 90 percent belong to PhRMA. Reports data on current disease prevention and elimination as result of drug research and development. Discusses increase in life expectancy as it relates to technology.
310	Swen	Continues presentation. Comments on demand for better health care and the cost of drugs relating to disease prevention.
400	Swen	Addresses technical differences and clinical results.
TAPE 66, B		
010	Swen	Continues presentation and offers examples of innovation and subsequent results.
042	Rep. Tomei	Comments on direct consumer advertising creating demand.
044	Swen	States no evidence to support alleged increase in demand due to direct consumer advertising.
053	Rep. Tomei	Questions purpose of advertising.
054	Swen	Explains impact of marketing. Discusses types of impacts as a result of direct consumer marketing.
117	Rep. Dalto	Comments on warning labels. Notes role of doctors in prescription consumption.
139	Swen	Responds and comments on the diet drugs marketing.
150	Rep. Barker	Comments on impact of marketing certain drugs.
159	Swen	Notes unintended response of consumer's to seek medical attention due to marketing.
178	Rep. Anderson	Compares consumer drive to that of dental patients.
185	Spencer	Relates personal experience with physician.
219	Rep. Tomei	Relates example of car sales to drug sales.
226	Swen	Responds that advertising is intended to sell drugs.
236	Rep. Anderson	Comments on the results of marketing help to support future drug development.
247	Swen	Concurs.
250	Rep. Dalto	Comments on promotional tools. Requests information on ratio of detailing to direct consumer advertising.
258	Swen	Reports figures for detailing and states that the cost include free drugs. Conveys that general promotional tools are used by all manufacturers,
290	Rep. Dalto	Comments on ratio of funds spent in other areas compared to drug manufacturers.
298	Swen	Indicates that Pfizer is in business to offer returns to shareholders. Requests criticisms should be put in perspective. Reiterates issues related to promotion of specific drugs.
349	Rep. Dalto	Reiterates expenditure ratios of detailing and direct consumer advertising.
361	Spencer	Clarifies regulations and role of detail representatives.

384	Swen	Continues presentation. Addresses issues related to closed formulas in which one drug is selected for Medicaid coverage.
TAPE 67, A		
010	Swen	Continues presentation on drug development. Speaks to timing of market.
018	Rep. Westlund	Inquires on regional based and locally developed formularies.
039	Swen	Notes restrictions are based on price of drugs. Comments on impact to future research. Addresses total health care costs as they relate to drug silos.
066	Rep. Westlund	Speaks to long term savings in health care.
069	Swen	Discusses health maintenance organization (HMO) incentives. Addresses risk sharing as it relates to acute cost elimination and long term care. Reviews formularies and cost savings.
111	Spencer	Addresses level of restrictions on formularies.
131	Rep. Westlund	Comments on solutions.
145	Swen	Remarks solutions lie in technology. Continues presentation. Discusses relationship of human genome research to drug research and development. Compares current research capabilities to that of 10 years ago. Notes risks of unprecedented measures.
195	Chair Kruse	Comments on effectiveness of targeted cures and market returns.
208	Swen	Relates impact of phenol-type research on treatment and market.
246	Chair Kruse	Questions phenol-typing and genome mapping as it relates to marketing and returns.
273	Swen	Responds that it provides the ability to sustain research and development.
303	Chair Kruse	Inquires on role of Federal Drug Administration (FDA) in shortening process.
308	Swen	Explains work with FDA. Concludes presentation on drug development. Notes international purchase price parity data. Expresses concern over short-term solutions in regard to long term cost controls.
396	Rep. Westlund	Inquires on poly-medication usage.
405	Swen	Speaks to drug interactions and reports that patient pharmacopoeia management is beyond scope of pharmaceutical manufacturing companies.
505	Chair Kruse	Closes informational meeting and adjourns at 11:05 A.M.

TAPE 68 reflects only overlap testimony from TAPE 67, A.

EXHIBITS

A – Informational meeting, Power Point Presentation, John Swen, 30 pp.