This paper was submitted for publication in the Genomic/Proteomic Technology Section of American Biotechnology Laboratory, Volume 21, Number 9, 24B-D, August 2003

030306 Costs in the Health Care Industry-You Have to Pay the Piper

It has been reported that illness-intervention costs rose 13.7% over 2001-2002 period. The breakout of the sources of increasing costs is given in Table 1. There is continuing discussion on this growth which may be second only to growth in the entertainment industry.¹ However this sector receives considerably more attention because of the non-recreational or involuntary need for much of the services.² This article speculates on some aspects of the growth of the first two items listed in the Table, drugs and devices and provider costs, which account for 40% of the increase.

As in all other successful industries the drug, device, and related industries direct their development resources to areas which provide the largest markets and the highest likelihood of success. The targets generally are the development of therapeutic interventions for treating lifethreatening conditions, minimizing the negative consequences associated with chronic or incurable diseases, or simply making folks feel better. The intent of these interventions is not only to increase life expectancy and improve the quality of life but also to help maintain a youthful-state of well-being and vigor. The success of these interventions is reflected in part in the graving of the population and the corresponding growth in assisted living and nursing home developments. The lives of many of the individuals in this aging population depend on the chronic use of these interventions, i.e., the use of the products is a significant factor in the increasing market. Poly-pharmacy is almost a way of life for many senior citizens over 75 years of age. In addition, the longer the products sustain you, the more products you tend use; i.e., declining health status parallels aging. This life sustaining-expansion strategy has been very successful in bringing about the growth of the pharmaceutical industry where 2001 profits for several of the large companies are given in Table 2. Although these amounts appear daunting they should be viewed from perspectives which include the mergers into mega-multinational firms and the return-on-investment. Graph 1 presents economic profitability data from various United Kingdom sectors. This graph shows that over this time period the profitability of the pharmaceutical sector has been relatively stable but not as remarkably profitable as some other sectors.

As noted above the profits in the pharmaceutical industry are rooted in large part in the increasing market demand that is linked to the increased life-expectancy or death-diversion arising from the use of those products. The longer the products help avoid debilitating illness and death the more products will be required to sustain the healthy state. In addition, the pharmaceutical industry invests very heavily in drug discovery and development to find new products which are safer, are more effective or address new illnesses.

¹ I include in the entertainment sector sports at all levels including car racing; music; television and related products; leisure travel; electronic games; non-work-related computer use; cameras; theme parks; gambling; dining-out; etc.

² The voluntary segment includes the non-therapeutic use of vitamins, health-foods, various interventions to address self-inflicted illnesses, cosmetic surgery, etc.

The individuals employed in these discovery and development efforts typically have advanced academic degrees including in many instances post-doctoral training. The US Bureau of Labor Statistics reports that half of all workers in drug manufacturing have a bachelor's, master's, professional, or Ph.D. degree—roughly double the proportion for all industries combined and their earnings are much higher than those in other manufacturing industries.³ Since entrance into advanced academic degree programs is highly competitive, these individuals have shown over the interval from kindergarten (or earlier) through their graduate training programs to be academically very strong in addition to being highly disciplined and achievement oriented. The pharmaceutical industry has been very successful in recruiting into their programs such highly competitive, successful people. The concept of a five-eight-hour day work week has no meaning to these individuals who have been disciplined through their academic training to consider a fifty-or-more-hour work week to be their norm. The majority of highly disciplined bright individuals succumbs to their personal material interests and expects an income appropriate for their accomplishments. This de facto makes the per-capita wage level in the pharmaceutical industry significantly higher than other manufacturing sectors. This same drive for remuneration appropriate to output has been a primary driver in the US labor movement and it permeates almost all walks of life. In the pharmaceutical sector this highly-disciplined competitive environment begins with individuals with that bent in the Board Rooms and then permeates the entire organization. Of course these highly-disciplined and competitive individuals also are essential to the success of this industry and are its builders.

In addition to the relatively high per capita drug-development personnel costs there is a large cost in the demonstration of clinical safety and efficacy (S&E) driven by societal demands for risk aversion as is reflected in FDA regulations. It should be noted that the S&E evaluation of symptomatic or condition interventions is less costly to demonstrate than preventative assessments; i.e., intervention studies on ill-populations vs well-populations. The 1954 Salk Polio Vaccine S&E preventative field study conducted by Dr. Thomas Francis, Jr.⁴ is an astounding example of such a study. "The Francis report was the culmination of a year-long field trial of the Jonas Salk vaccine, unprecedented in its scope and magnitude. Using a double-blind method of statistical analysis, where neither patient nor administering physician knew if the inoculation was the vaccine or a placebo, 440,000 children were given the vaccine and 210,000 the control substance. In addition, Francis agreed to a controlled observation trial involving more than 1 million children participating either as knowing recipients of the Salk vaccine or as noninoculated children placed under observation for comparison. All told approximately 1,830,000 children in 217 areas of the United States, Canada, and Finland were involved in the field trial."⁵ By contrast an S&E study on a cancer intervention may be conducted on relatively few of the available members of the target population. Although the cost of conducting a narrow targetedpopulation S&E clinical study will be significantly less than a broad-population study, the market potential also is markedly less, which requires the amortization of costs on a smaller market thereby making those drugs more expensive.

³ See <u>http://www.bls.gov/oco/cg/cgs009.htm</u> and http://pubs.acs.org/isubscribe/journals/cen/76/i42/html/ffind.html

⁴ At that time Dr. Francis was Director of the Poliomyelitis Vaccine Evaluation Center, University of Michigan (Ann Arbor, MI).

⁵ See the University of Michigan Library archives at <u>http://www.med.umich.edu/HCHS/articles/PolioExhibit/Francis.html</u> and <u>http://www.med.umich.edu/HCHS/articles/PolioExhibit/Evaluation.html</u>

Focusing clinical studies on narrower targeted interventions through pharmaco-genomics/genetics screening tools will reduce the clinical S&E population requirements but these populations will also be proportionately smaller markets. These targeted products likely will present better and more successful interventions but it is unlikely that the per-treatment or longterm costs will be less than the "block-buster" products. It also is unlikely that the regulatory requirements for targeted-population S&E studies will significantly reduce these evaluation costs. However, new technologies to better screen target populations and assess the success of interventions may change these requirements.

The second largest contributor to the rising costs has to do with the delivery of health care. The delivery of illness intervention is conducted under the auspices of physicians who graduate from medical schools. Entry into medical schools is extremely competitive. The American Association of Medical Colleges estimates that only 50% of the applicants are accepted into the medical school programs.⁶ In addition, attendance at medical schools is expensive and over 80% of the graduates have taken loans to fund their education; in the year 2000 graduating class the median debt was \$95,000.⁷ In addition to having highly competitive admissions to expensive programs, the medical schools require a very high level of self-discipline to achieve the degree. Following graduation from medical school, physicians typically enter internships or residency appointments before going on to practice. These residency/internship positions on occasion have required the individuals to work 80+ hours per week at their hospital assignments.⁸ These work levels have given rise to a union movement to force a reduction in these time commitments. As in the earlier example of the employees in the pharmaceutical industry, the physicians are required to be even more academically competitive and goal-oriented than the pharmaceutical research and development staff, and they also have incurred a higher debt level upon graduation. As with the highly-trained individuals in the pharmaceutical industry, the physicians expect to receive a level of remuneration which rewards their academic discipline and ability to provide services. Table 3 presents a 2001 tabulation of physician median compensation by specialty which ranges from \$140,000 for Family Practice to \$362,000 for Cardiac Surgeons. Following earlier trends it is likely that these compensation levels are higher in 2003. In addition to having spent significantly more time in training, physicians spend longer hours at work; a 1996 survey indicated that the average physician worked 56 hours per week.⁹ This highlights that the illness intervention delivery is controlled by very-bright academically-disciplined competitive individuals who finish medical school with a significant debt load and who work long hours in their practice. Once again bright, highly-motivated, and disciplined individuals, who work long hours, in general expect to receive compensation commensurate with these characteristics and requirements.

Conclusions: The rising costs of illness intervention are driven in part by an increasing demand arising from people living longer because of those interventions in addition to an expanding market driven by government Medicare-Medicaid and private sector insurance programs. In a free market, a growing demand drives increasing costs unless significant economies of scale or

⁶ See <u>http://www.aamc.org/students/considering/gettingin.htm#Tough</u>

⁷ See <u>http://www.aamc.org/students/considering/financial.htm</u>

⁸ See <u>http://www.calcsea.org/president/csea_voice/1999121005.html</u>

⁹ See http://www.ama-assn.org/sci-pubs/amnews/pick 98/anna0713.htm

technological leverages can be developed to create more product and service. This added demand is placed on our pharmaceutical and health care delivery industries which are staffed with some of the society's brightest, most-disciplined, and highly competitive individuals. These individuals in general expect compensation which corresponds to their ability and disciplined performance. In a civil society there is nothing illegal or immoral with defending your economic interests or receiving compensation levels within the limits of the law.

This cost conundrum could be addressed by either reducing demands or costs. A reduction in demand is unlikely and/or unacceptable. Thus cost reduction is the only viable option to control the outlays required for the illness interventions. A significant cost reduction in pharmaceutical products may be effected by reducing development costs. This in part could be accomplished through improved target design for the preclinical and clinical development studies. It is likely that significant improvements in target design could be effected by the application of artificial intelligence scanning engines to markedly improved toxicology relational databases. Better target design coupled with improved pharmaco-genomic/-genetic screening tools perhaps coupled with in vitro cell-based testing could reduce the clinical study population requirements.

Intervention delivery costs could be reduced in part by the development of improved personal assistance medical devices that provide greater levels of automation which would increase independence and reduce service requirements. The development of more automated health assessment tools perhaps associated with pharmacies could also increase availability and reduce costs. The development and application of improved information-technology based individual health records coupled with demographic trends and pharmaco-genomic/-genetic information might also help better target delivery needs.

Since it is unlikely that the demand for health services will decline the only option to help reduce the growth of costs is through improved development targeting, increased automation and increased economies of scale. These same techniques have been exploited very effectively in controlling costs in the electronic industry.

Table 1: Growth in Healthcare Costs*		
Source	% of the increase	
1. Drugs, devices, etc.	22	
2. Rising provider expenses	18	
3. Inflation	18	
4. Government regulations and mandates	15	
5. Increased consumer demand	15	
6. Litigation and risk management	7	
7. Other	5	
* See http://sago.tamu.edu/shro/newsnotes/nnoct02-chart.PDF		

Table 2: Drug Company 2001 Profits*		
Company	In millions US	
Pfizer Inc	\$ 7,788	
Glaxo SmithKline	\$ 7,325	
Merck & Co	\$ 7,282	
Bristol-Myers Squibb	\$ 5,242	
Abbott Laboratories	\$ 1,550	
*See http://www.guardian.co.uk/Print/0,3858,4607412,00.html		

Table 3: 2001 Physician Mean Revenue and Compensation			
Specialty	2001 median revenue	2001 median compensation*	
Cardiologist (surgical)	\$731,904	\$362,209	
Family practitioner (non OB-GYN)	\$287,239	\$146,601	
General surgeon	\$497,633	\$257,509	
Internist	\$288,494	\$149,020	
OB-GYN	\$501,634	\$231,000	
Orthopedic surgeon	\$678,186	\$354,184	
Pediatrician	\$321,935	\$150,000	
* Pre-tax earnings after all expenses; the median is the point at which half made more, half less			
Source: Two surveys of earnings and expenses published by Medical Economics magazine; USA TODAY research; From USA Today, March 5, 2003, p3a			



