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A View From Inside Industry: A Response to Professor Walker's Challenges

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INTRODUCTION

Successfully dealing with the four challenges described by Professor Walker is critical to both the effective management and the financial stability of the research-based pharmaceutical industry. The interplay of government, industry, and the consumer is also a critical factor in determining whether these challenges can be met. The very character of these three participants (government, industry, and consumers) has changed dramatically in recent years. Governments, while historically involved in the drug review and approval process, have become progressively more active in providing health care to their populations; in some countries this involves establishing standards of care. Industry consolidation, as discussed by Professor Walker, has resulted in fewer but larger providers of pharmaceuticals, whose increasingly large research expenditures are being directed both at newly emerging diseases, such as AIDS, and diseases for which current treatment is considered to be less than satisfactory, such as depression and malignancy. Finally, the traditionally recognized consumers for pharmaceutical products have been members of the medical profession: physicians and surgeons. In recent years, there has been a dramatic redefinition of "consumers" to include managed care organizations, governments, buying groups, pharmacy benefit managers, and patients themselves.

These changes in the nature of the principals involved in the pharmaceutical interaction have been accompanied by three increasingly important developments within the industry. The first of these developments

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is the requirement that, prior to approval, new pharmaceutical agents must be shown not only to be effective and safe, but also must conclusively be demonstrated to be cost-effective and/or to provide an improved quality of life. This requirement is now mandated in Australia and Canada and is certain to be required eventually in other countries.

The second development is the recognition that new drugs must provide significant advances over their predecessors. In light of the redefinition of potential consumers of pharmaceutical agents, small increments of change will not be rewarded by the marketplace and, in simple terms, people will no longer pay for “me-too” drugs. The final important development within the pharmaceutical industry is the understanding that the targets of new drug development, particularly malignancy and diseases of the central nervous system, will require significantly greater expenditures and the application of considerably more advanced technology than many, if not most, of the infectious, cardiovascular, and gastrointestinal diseases which have yielded to pharmaceutical innovation in the past. It is in the context of the changing nature of the challenges faced by the global pharmaceutical industry and the changing nature of its stakeholders that I will respond to Professor Walker’s analysis by reflecting on my experiences inside a global pharmaceutical company.

I. REMAINING PROFITABLE

Professor Walker describes vertical and horizontal integration, mergers and acquisitions, and increasing expenditures on research and development (R&D) as means utilized by the pharmaceutical industry to maintain current levels of profitability. While horizontal and vertical integration have increased, these are not the only strategies available to address the profit challenge. Eli Lilly and Company (Lilly) has chosen an alternative strategy to profitability that is not related to company size or integration. The dominant factor in Lilly’s strategy to remain profitable is pharmaceutical innovation. We define pharmaceutical innovation as the series of processes of value creation that convey a biomedical discovery into a pharmaceutical product that is desired—and, therefore, will be paid for—in the marketplace.

Lilly believes that, with R&D efforts directed toward the goal of profitable pharmaceutical innovation, we can provide benefits to shareholders, employees, and patients alike. The companies that will be financially successful are those that can deliver truly innovative solutions to health care

problems. This type of innovation cannot be automatically achieved simply through horizontal integration, vertical integration, or increased R&D expenditures. Professor Walker noted that the profit and innovation challenges are interdependent, and Lilly's strategy reflects the critical importance of pharmaceutical innovation to profitability.

II. CARRYING OUT INNOVATIVE DISCOVERY RESEARCH

Professor Walker has documented the major advances in therapy since 1980. He has mentioned, and I will strongly emphasize, two developments: the disappearance of the "not invented here" syndrome and the advent of new technologies. Historically, research in the pharmaceutical industry was rather insular and, perhaps, arrogant. It was believed that industry was the prime residence of expertise related to drug discovery and development, and that there was little to learn from others. Fortunately, the past ten to fifteen years have witnessed the virtual disappearance of this attitude. There are few, if any, major research-based pharmaceutical companies that do not have a significant number of research alliances with universities, institutes, and small biotechnology concerns. While the majority of these alliances are with entities in the United States, there are also rapidly growing collaborations with organizations in Europe and the Asia-Pacific region. Just as the market for pharmaceutical products has truly gone global, the search for innovative new drugs is also taking shape as a global endeavor involving researchers and companies at many different levels of an economy in many different countries. What we are witnessing is the decentralization and globalization of pharmaceutical R&D.

The advent of newer technologies has greatly enhanced the opportunities for innovation. Within the past ten years, the field of genomics has arisen. This field holds the promise of understanding the genetic basis of a wide range of diseases and offers for the first time the possibility for innovative pharmaceuticals to target the precise genetic defect in a disease agent. Combinational chemistry and high throughput screening¹ now enable us to test hundreds of thousands, even millions, of chemical compounds in the period of

1. Until recently, chemists working with traditional tools could assemble new molecules only one at a time. However, by using combinatorial chemistry, those same chemists can now assemble thousands of new molecules within days. They are now synthesizing compounds 100 times faster than in the past and are screening them faster to find the most promising drug candidates.

time in which only hundreds or thousands of compounds could have been tested in the past. These technologies have already produced “drug candidates”, chemicals that have the potential to be developed into pharmaceuticals, which may never have been identified or, if identified, would have required significantly longer periods of time to identify. New technologies might help reshape the nature of pharmaceutical development, as new technologies have revolutionized other economic sectors, such as telecommunications. In addition, these new technologies will accelerate the decentralization and globalization of pharmaceutical R&D already taking place in the industry.

III. BRINGING NEW MEDICINES MORE QUICKLY TO THE MARKETPLACE

As noted by Professor Walker, it has historically required ten to twelve years to develop a new pharmaceutical agent. Virtually all major research-based pharmaceutical companies have recognized that such a development time is unacceptable from the perspective of consumers, company management, and shareholders. Most companies have embarked on major “reengineering” efforts in an attempt to shorten this time.²

At Lilly, we have made a commitment to reduce our drug development time from our historical duration of 4700 days (twelve to thirteen years) to 2500 days (seven years). At the present time, through reengineered activities and without a substantial increase in resources, we have been able to move from 4500 days to 3300 days. The application of new technologies, from robotics to information technology, has been central to the advances made thus far. Even greater advances will be possible in the future as science progresses. For example, if the possibility of using non-animal systems to study safety (toxicology) were to become a reality, the development time required to bring a new drug to market would be reduced even more.

IV. ENSURING A RAPID AND EFFICIENT REVIEW PROCESS

As Professor Walker indicated, ensuring that the regulatory review process is both rapid and efficient should be a responsibility shared by the pharmaceutical industry, regulators, and consumers. The pharmaceutical

2. Development time is defined as the time from formation of a cross-functional team responsible for development of a promising new chemical until launch into two-thirds of the world's market.

industry must utilize all available technology in order to provide complete, relevant, and scientifically valid information to regulators in an accessible and understandable form. When regulating new drugs, regulators must require only that data which is necessary to make reasoned decisions concerning the efficacy, safety, cost-effectiveness, and/or quality of life attributes of the new drugs. Consumers must exert appropriate pressure on both the pharmaceutical industry and regulators to ensure that appropriate data is efficiently reviewed; as a result, useful drugs will not be denied to patients for extended periods of time.

Recently, two developments have provided hopeful indications concerning the speed and efficiency of the drug review process. The formation of the European Medicines Evaluation Agency provided a centralized procedure of review by which it is possible for there to be virtually simultaneous approval for marketing in all fifteen European Union member states.³ On a more global basis, the International Conference of Harmonization (ICH), which has existed for approximately four years, brings together regulators and pharmaceutical manufacturing associations from the United States, Japan, and the European Union. The goal of the ICH is to use input from industry to obtain as much harmonization as possible among the drug approval requirements of the parties involved. To date, a significant amount of progress has been made: guidelines in the three geographical areas have been modified, and the process for even more enhanced transparency among regulations across the jurisdictions involved in the ICH process has been implemented.⁴ Such international harmonization has been, and will continue to be, an important factor in streamlining the regulatory review process. The need for regulatory harmonization at the intergovernmental level mirrors the need for more creative and collaborative R&D approaches in the industry. Just as pharmaceutical companies abandoned the "not invented here" syndrome, national regulatory agencies learned to operate in a global system of pharmaceutical regulation.

3. Evelyne Friedel & Michael Freundlich, *European Community Harmonization of the Licensing and Manufacturing of Medicinal Products*, 49 FOOD & DRUG L.J. 141, 163 (1994).

4. Joseph Contrera, *The Food and Drug Administration and the International Conference on Harmonization: How Harmonious Will International Pharmaceutical Regulations Become?*, 8 ADMIN. L.J. AM. U. 927, 939-55 (1995).

CONCLUSION

The four challenges facing the pharmaceutical industry described by Professor Walker are difficult and interdependent challenges. Whether the strategy be horizontal integration, vertical integration, or Lilly's internal reorientation toward pharmaceutical innovation, the global pharmaceutical industry is searching for ways to meet these challenges. Professor Lasagna is correct to emphasize the difficulty of fully meeting these challenges, but it is my experience at Lilly that much has already been done to bring the industry into a new era at the governmental, company, academic, and consumer levels. While old ways are being cast aside, new opportunities are being created in the laboratory, the physician's office, the board room, and the government's regulatory agencies. However, it must be understood that it is only through a partnership among industry, academia, government, and consumers that the pharmaceutical industry will be able to provide safe, effective, and affordable globally-available responses to the threats to human health in the global era.