On Being a Neurologist in Industry

David Leppert, MD[1,2] and Robert Glanzman, MD[3]

Neurologists in the pharmaceutical industry have an attractive and rewarding career path that offers the chance to participate in large projects, contribute directly to clinical breakthroughs in drug development, and translate biomarker research into applied practice. This article describes the different and common features of corporate compared to academic environments, and highlights the key factors necessary for success in the business world. Integrity, communication skills, an open-minded attitude, and an ability to handle stress and manage complex organizational structures are prerequisites that enable physician–neuroscientists to pursue successful and exciting careers in the corporate environment.

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"The role of neurologists in the pharmaceutical industry has expanded considerably during the past decade" is the opening sentence of the sole article that specifically describes what neurologists who work in the corporate environment actually do.[1] Since its publication in 1994, this topic has received little attention, despite increasing numbers of neurologists working in industry, enormous progress in the development of new therapies for neurological diseases, and profound changes in the role of the medical function within corporations over the past 2 decades.

In this article we will examine the roles neurologists currently play in the biopharmaceutical industry, discuss careers in the corporate environment, and compare these with careers in the academic world. However, it is important to remember that "… the underlying motive that drives the effort and commitment of most people in both camps is the desire to improve the lot of patients."[2] An individual's skills, preferences, and opportunities may therefore determine where a neurologist chooses to contribute best to this goal.

All who work toward the development of better therapies for patients with neurologic disease are faced with a multiplicity of challenges, including:

- Difficulty in translating an emerging understanding of the pathophysiology of neurologic disease into practical therapies[3–6];
- Confronting unmet medical needs for patients in the face of limited resources in the public and private sectors[7]; and
- Dealing with a lack of consensus with respect to how an ethically sound and productive collaboration between academia and the pharmaceutical industry should be structured and maintained, recognizing that both parties are interdependent if progress in basic research and applied medicine is to be achieved.[2,4,8]

As scientists invested in improving the lives of patients with neurologic disease, neurologists in industry often serve as intermediaries between academia, regulatory agencies, and patient advocacy organizations. They also act internally as creative forces in the development of novel therapeutic strategies and as champions for prioritizing patient needs among competing corporate priorities.

Work Setting and Motivation to Work in the Pharmaceutical Industry

The biopharmaceutical industry has recognized neuroscience as an area of enormous unmet need, in which therapeutic breakthroughs are realizable, due to advances in the understanding of human genetics, molecular and cellular biology, and neuroimaging.

Conversely, since the late 1990s the rate of registration of new molecular entities (NMEs; also called new chemical entities [NCEs]; an NME or NCE is, according to the US Food and Drug Administration [FDA], a drug that contains no active moiety that has been approved by the FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic

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Address correspondence to Dr Leppert Group Medical Director, F. Hoffmann-La Roche Ltd, Building 74/3W.306A, Grenzacherstrasse 183, CH-4070 Basel, Switzerland. E-mail: david.leppert@roche.com

From [1]F. Hoffmann-La Roche Ltd, Basel, Switzerland; [2]Department of Neurology, University of Basel, Basel, Switzerland; and [3]Purdue Pharma LP, Stamford, CT.

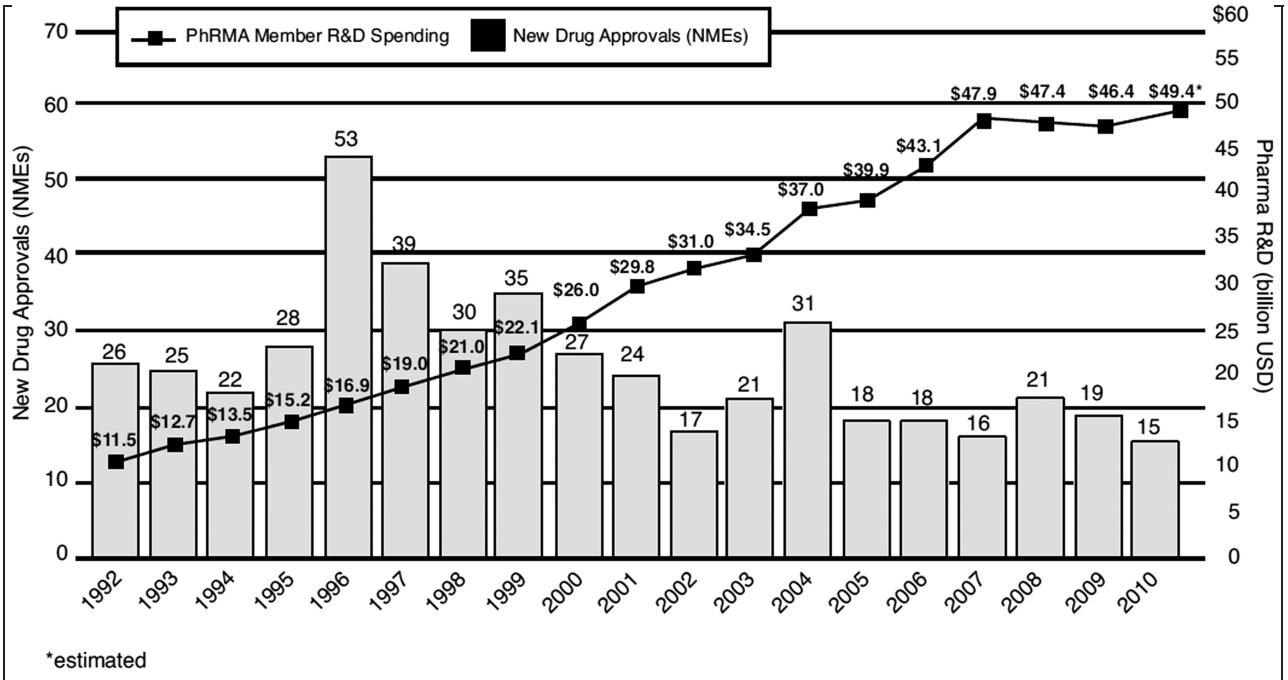

FIGURE : Annual research and development spending versus new drug approvals, 1992–2010. NME = new molecular entity; PhRMA = Pharmaceutical Research and Manufacturers of America; R&D = research and development; USD = US dollar.

Act [http://en.wikipedia.org/wiki/New_molecular_entity]) appears to be stagnating, both in neurology and in other therapeutic areas (Fig).[5,7,9,10] This lack of productivity (as reflected by the ratio of the number of NMEs per dollar of investment) is an increasing concern in the scientific community[3,11] and across society.[12]

If it is true that there has been a relative decline in the trajectory of successful drug development, a potential structural cause relates to the settings in which modern biopharmaceutical research is often carried out. For many organizations, the biomolecular revolution of the 1960s led to the separation of basic and clinical research. Molecular medicine became an independent entity, carried out by laboratory scientists who were not primarily focused on translating their achievements into new medicines.[4] Conversely, the pharmaceutical industry has withdrawn from funding in-house basic research, and the concept of integrated drug development has been largely abandoned. This is illustrated by comparing the number of Nobel Prize winners in physiology or medicine with those in physics who work in a corporate setting. The last Nobel Prize winner in medicine working in industry dates back to 1993, whereas in physics 4 of 30 laureates in the last decade (2000–2010) made their achievements working in companies.[13]

Modern drug development is an expensive, complex, time-consuming, multifunctional process, requiring scientific, biostatistical, regulatory, pharmacosafety, operational, commercial, and legal expertise. This level of complexity makes it virtually impossible for physicians in academia or public agencies to develop and implement a full drug development program. Conversely, there is a pressing need in industry for physician–neuroscientists, who can integrate broad areas of knowledge and have hands-on experience in clinical neurology, experience in clinical and/or laboratory research, knowledge of the molecular basis of neurologic disease, and a grasp of the power of modern genomic and proteomic analytical techniques (-omic platforms), and of neuroimaging. Additional, critical competencies are in communication and people management. Scientists in clinical development are commonly leaders of complex, matrixed teams, comprised of leaders from multifunctional groups, as outlined above. Successfully managing and leading such teams of leaders requires a significantly different skill set from that necessary to be successful as a pure bench scientist, but perhaps a skill set that is similar to the operational and managerial skills required to lead large, multisite research projects in academia.

The structural gap created between basic research efforts in identifying potential molecular targets of disease and the complex drug development process is commonly referred to as *translational medicine*, and the traditional paradigm to bridge it lies in a bench-to-bedside approach. Although this has been described as the "valley of death, where neither basic researchers … nor physicians … are keen to venture,"[4] we perceive this as an opportunity for physician–neuroscientists, both in academia and in

industry. The NIH and similar institutions in Europe have begun initiatives[3,14] funding clinician–researchers to engage in translational medicine programs. Whether government institutions, such as the NIH, are well suited to design and implement translational projects related to drug development is debatable. Clearly, however, the resource capacity to implement bench-to-bedside approaches is greatest in industry, as the bulk of funds for translational and clinical biomolecular research comes from pharmaceutical and biotech companies.[5,7] In the United States, the fraction of research funding that comes from industry is highest for neuroscience in both relative (55%) and absolute (7.8 billion US dollars in 2005) terms, compared with other therapeutic areas.[5,9] There are reasons, specific to neuroscience, why drug development in this field is particularly difficult. As opposed to therapeutic areas such as oncology where discrete clinical result categories (eg, survival) are the rule, many neurological and psychiatric endpoints depend on measurements that are psychophysical in nature (eg, pain), rater dependent, and based on descriptive clinical phenotypes (eg, clinical disability in multiple sclerosis), or validated only within specific cultural and linguistic settings (eg, cognitive function in dementing illnesses). These factors lead to increased variability in efficacy measurement, heightened placebo effects, and a general decrease in the probability of technical success for experimental therapies. The development of reliable, clinically meaningful, generalizable, and approvable endpoints, as well as development of predictive biomarkers that supplement phenotypic clinical outcomes at earlier stages and with greater specificity, is critical if we are to overcome current limitations. To increase the efficiency of drug development, academia, regulatory agencies, and industry will need to collaborate more closely to develop better measures of efficacy in neuropsychiatric diseases. Another need, which is not restricted to neuroscience, is to improve training and career development for those who endeavor to become physician–scientists, as they represent the primary personnel resource qualified to run clinical development programs.[15]

The corporate environment provides a unique opportunity for those neurologists who want to take part in the translation of innovative science into novel therapies and diagnostics that improve the lives of patients. At its best, industry can provide rich analytical and logistic platforms coupled with adequate financial resources for these tasks, attributes that often do not exist in academic settings. Designing and executing studies aimed at identifying new biomarkers or demonstrating the safety and efficacy of a candidate drug are both exciting and intellectually challenging pursuits. Those who have experienced the positive result in a biomarker study, or the unblinding of positive data in a phase II/III clinical trial, often comment that this is more than a source of great satisfaction—it is a particularly joyful, once in a lifetime experience.

Despite these immense opportunities, only a small minority (ie, 2% according to the American Academy of Neurology[16]) of board-certified neurologists work in the corporate sector. Many pharmaceutical companies have now recognized the need to recruit more neurologists on staff. Both authors decided, at a certain time in their academic careers, to move to industry, based on a motivation to make a positive impact on the future of large numbers of patients and a belief – subsequently confirmed – that they could effectively practice outstanding translational medicine in this environment.

Role of Neurologists in the Pharmaceutical Industry

Typically, neurologists in industry find themselves in *clinical development* (Table), the corporate department where the clinical development plans required for registration of new compounds are strategized and implemented. Here they are positioned at the interface between basic science colleagues in preclinical/early development and business colleagues in sales/marketing functions.

In clinical development, neurologists spend most of their time reviewing and analyzing data to conceptualize, plan, and execute late phase clinical development programs. In this process, the neurologist, together with other stakeholders on the project team, continuously monitors incoming safety and efficacy data and assesses whether the benefit/risk profile for the drug continues to be such that it will be approvable by regulatory authorities, will be prescribed by treating neurologists, will be reimbursed by payers, and will ultimately benefit patients. Another important task is conceptualizing translational studies in support of the clinical development program, providing critically important adjunctive, scientific data in related areas such as imaging, electrophysiology, and fluid biomarkers. These internal duties run in parallel with duties that interface outside the company, such as presenting at investigator meetings, working with academicians in study steering and independent data monitoring committees, presenting to health authorities (such as the FDA and European Medicines Agency [EMA]), and acting as a liaison to external, expert peers.

Preclinical development involves sciences related to pharmacological drug effects and toxicology in animals. Neurologists serve as an important interface to these scientists, relating these models to human disease. Recent years have brought a shift away from animal models in many neurologic disease areas, based on the notion that the most relevant models for human disease are humans

TABLE : Networking Structures (Matrix) of a Physician–Neuroscientist

Interactions	Preclinical Development	Clinical Development	Business
Company internal	Technical development (compound formulation), preclinical safety/toxicology	Regulatory, pharmacology, biostatistics, clinical operations, clinical manufacturing, pharmacovigilance/safety, regional medical functions	Marketing/sales, health economics/ outcomes research, legal/ intellectual property
Company external	Academic collaborations (eg, mode of action studies)	Health authorities/regulatory agencies, study steering committees, independent data monitoring committees, clinical investigators, institutional review boards/ethics committees, clinical research organizations (service providers for clinical trials)	Payor organizations, patients advocacy organizations, external marketing support agencies, external advisory boards

Table describes the internal (row 1) and external (row 2) business partners a corporate-based physician–scientist in charge of a drug development program is likely to interact with along the continuum (columns 1–3) of drug development. In a practical sense, the distinctions between preclinical development, clinical development, and business are only relative, as internal representatives of all these branches are typically involved in all phases of drug development, albeit to various degrees.

themselves. This has led to a more prominent role for biomarker research in preclinical development, and the neurologist is crucial for relating those results to clinical measures and the proper planning of next-step experiments. The -omic platforms provide insights in the molecular mechanisms of human disease, but at the price of logistical and interpretational challenges.[17] Neurologists in industry need to be fully acquainted with the potential and also the limitations of these tools, to provide salient advice and to prevent costly experiments that do not deliver relevant answers to the critical questions at hand.

Business-related activities are typically driven by nonphysicians, or physicians who came to industry early in their careers. Business colleagues are responsible for positioning the FDA/EMA-approved attributes of a drug for a disease, educating the community about these attributes, and selling the drug to payers and physicians at large. Neurologists often play the role of advisors to this corporate branch. Their knowledge of the pathophysiology of disease helps the company to determine whether a particular drug target makes sense in the context of commercial constraints, and how the development of a candidate compound might be approached. They are the primary point of contact when it comes to explaining the real world pros and cons of competitor drugs, and the therapeutic landscape in general, which may vary considerably among countries and continents. Lastly, in recent years, health care economic considerations have become a prominent aspect in the planning of development programs where expert medical input is needed. An important skill for any neurologist working in industry is the ability to translate complex, clinicoscientific concepts into easily understandable language, to effectively educate and work within diverse corporate functions.

Regulatory processes such as writing study documents, answering health authority questions, and attending formal meetings with the FDA and EMA for registration and marketing approval of a drug are highly complex and almost as resource-intensive as the planning of clinical studies. The language, terminology, and biostatistical concepts used in the regulatory environment are very different from those physicians are traditionally acquainted with, making this an area where neurologists typically learn on the job. As marketing and regulatory functions are gravity centers for corporate decision making, it is important to become familiar with their functions, to be able to convey a rational, medical–scientific position effectively.

For the individual neurologist, it is this very interface within a multifunctional matrix that leads to effective contributions. This requires that he/she becomes not only thoroughly acquainted with, but also masterful in operating within, a set of (what often appears as unnecessarily rigid) processes, regulations, and compliance procedures, specific to the corporate pharmaceutical industry.

A smaller number of neurologists work in small biotech companies or start-ups. These companies are often founded on an attempt to turn a single, novel scientific concept into a new therapy or diagnostic device. The internal organizational structure of these entities is typically restricted to the core activities of early development, with the consequence that many processes are outsourced to external service providers, for example, clinical research

organizations. The small biotech corporate environment is typically less structured than in large pharmaceutical companies, with single employees (potentially) performing multiple functional roles. A further difference is the need to interact deeply with venture capitalists to ascertain and negotiate the necessary financial resources to implement an early development plan, a process not needed in large, self-funded pharmaceutical companies. At a later stage, negotiations with pharmaceutical companies that have the capacity to take a drug or diagnostic tool through registration trials are required. The success of such licensing deals depends not only on negotiating skills but also on the ability to deeply understand and crisply communicate the pharmacologic findings as well as the practical medical implications of the approach, areas in which experienced clinicians can contribute greatly.

Opportunities and Risks (and How to Contain Them)

The many opportunities and risks assumed by neurologists in industry have been previously outlined,[1] and all the points raised there remain valid today. We reiterate some of them here, based on our personal grading of importance, and we mention some new aspects that have emerged over time.

Working Environment

Nonspecialized physicians who join industry immediately or shortly after general medical training would most probably enter operational, marketing, or management positions. In contrast, senior neurologists are more likely to work predominantly as physician–neuroscientists and will generally be viewed as internal experts and key opinion leaders. In such positions, working cross-functionally with a variety of experts in a development team is an exciting and enriching experience. The flip side of this can be a perceived loss of independence and decision-making autonomy. Because the successful development of new drugs is the coordinated product of many specialized areas of expertise, success depends on good communication and cooperation with multiple team members, where adherence to timelines and formal working processes is mandatory. In the highly regulated environment of drug development, strict adherence to formal standard operating procedures is not negotiable. The type of pressure a neurologist in academia may experience intermittently, in the course of an annual grant renewal submission, is the daily norm in the corporate environment. Neurologists and other expert physicians may work under the direction of managers who are not medical experts. Corporate decisions are based on many considerations, not all of which directly relate to patient care, and this type of multifaceted decision-making process can be quite disconcerting and off-putting to a clinician. Patience, thick skin, strong negotiation skills, championing patients' needs, and seizing opportunities at the right time are the best ways to master these situations. In our experience, good medical–scientific rationales tend to prevail over time.

Lifestyle, Remuneration, and Job Security

Lack of direct responsibilities for patients and absence of out-of-office-hours work (night calls, attending) seem, at first glance, attractive advantages of the corporate versus hospital working environment. However, clinical project teams may be located across the globe, necessitating intense travel for internal meetings. This is in addition to travel for external meetings with academic peers, regulatory agencies, and so forth, so that travel can easily consume 25% of the working time of a neurologist in managing a project team. It is not uncommon for neurologists working in global development organizations to spend >30% of their nights away from home. Despite not being involved directly in treatment of individual patients, a typical responsibility of neurologists on a clinical project team is that for the safety and well-being of patients in their studies, a responsibility not different from that of a treating physician of an individual patient, except on a larger scale. Additionally, tight timelines and unforeseen events can often mean that neurologists in industry work late into the evening and on weekends.

There is a perception that the remuneration in the corporate environment is significantly higher than that in academic settings. This is not entirely correct, based on comparisons within North America and Western Europe. Corporate remuneration in large pharmaceutical companies includes a variable salary component of 20 to 30%, a feature not typical in the academic setting. This component depends on personal, departmental, and corporate annual performance. Slightly higher base salaries in industry in comparison with comparable job responsibilities in academia, plus incentive remunerations (designed to keep high-performing colleagues from leaving the company) may add up to as much as a 30% relative advantage of industry. However, these factors need to be balanced against advantages in the academic setting that include a greater likelihood of annual salary increases and long-term factors such as job security and better retirement benefits. In biotech companies, the wages tend to be less; this is compensated for by a larger share of stock options, which in this setting typically represent an income at high risk that becomes valuable only with the successful completion of a program and licensing to an external partner. In essence, financial considerations

should not be the deciding factor for a neurologist to pursue a career in industry.

Job insecurity has become an increasing concern in the corporate sector in recent years. Several large pharmaceutical companies have moved away from drug development in neuroscience because of the high cost of these development programs, failed trials, and difficulties in attaining successful drug approvals (see Fig).[18] Clinical development plans in neuroscience tend to be large, expensive programs, often with soft endpoints and significant placebo effects, making failed studies all too common, even with drugs known to be therapeutically effective. Academicians may be sensitive to this uncertainty and may therefore not feel comfortable with a career in industry. Neurological diseases remain an area of huge unmet medical need, and with the aging of the global population this trend is likely to continue. In industry there is probably more inherent job insecurity than in academia; however, the impression that the termination or failure of a specific program is likely to result in loss of employment is not correct. For an academic neurologist who is invited to apply for a corporate job, a number of issues should be considered. Does the specific development project address an unmet medical need? Is it scientifically purposeful and tractable? Is it intellectually and emotionally attractive? Does the program lie within my area of expertise? Does the company have a portfolio with several compounds that can survive the normal attrition that occurs in drug development? Is the company committed to the field of neurology and neuroscience? Corporations also vary considerably in terms of culture, especially when comparing small biotech and large biopharmaceutical companies. Does this company possess the team spirit and the quality of colleagues that will make this an exciting and intellectually stimulating place to work?

Maintaining Academic Standing

In most instances, the transition from academia to industry requires giving up individual patient care, independent research, and teaching activities. This means that clinical skills and academic standing may fade over time. This may not only be a challenge for the neurologist's self-esteem and self-actualization but could threaten his or her image within the company as an internal expert. In the past, companies traditionally allowed physicians a half day per week of clinical or other academic activity. However, given the increasing work load and time pressures in recent years, this has become less practical. Academic visibility may be served by supporting research work and coauthoring academic publications that are independent of the work done in the corporate environment, and by teaching at one's former academic institution. As plans in industry commonly require last minute changes on a regular basis, teaching duties are easier to coordinate than clinical responsibilities. It is important to set realistic goals, and to consider restricting one's aspirations to 2 of the 3 "triple-threat" domains (teaching, independent research, clinical activity).

There is a circumstance in which maintenance of clinical expertise may be essential: if a physician–scientist wants to keep the door open for a return to academia at a later stage of his or her career. In considering the change to industry, the academic candidate should be aware how this may limit their options for returning. Although there is hope that "the margins between academia and industry … are likely to blur,"[19] this can rarely be achieved for individual career paths. Up to now, "the way back from industry to academia is yet a narrow path,"[2] and this is likely to remain so in many settings.

Intellectual and Ethical Conflicts

Numerous articles have reviewed examples and their consequences when physicians fail to appropriately manage intellectual and financial conflicts of interest,[20–25] creating important professional risks, both in industry and academia. In academia, investigators are at risk of overemphasizing their findings to increase the chances of grant approval, publication in high-profile journals, or promotion. For physicians in industry the same temptations apply, with the difference that grant approval is replaced by budget allocation for development of a specific project and/or corporate support to an entire clinical development plan. The similarities between the 2 are even greater when academic institutions become owners or participants in intellectual property (IP) rights for drug targets. However, whereas IP rights in academic institutions may also be owned by individual researchers, this almost never applies to corporate employees. Although physicians in the corporate setting typically participate in stock option plans provided by their employer, the degree to which such incentives bias the behavior and judgment of individual physician–scientists is in our view quite small.

Maintaining strict objectivity in data evaluation and interpretation, high ethical standards, and maximum transparency are crucial to keeping one's standing within industry and helping to avoid pressures from both the inside and the outside. In our view, this has become easier to achieve over time, as rigorous networks of checks and balances created by governmental oversight, relations with patient advocacy groups, and probing by media all help to ensure safeguards that promote the maintenance of high ethical standards. Although some of these bodies

may be perceived as sources of bureaucracy and constraints on entrepreneurial freedom, in the long run they protect individuals, corporations, and the society at large.

For an individual, personal credibility in the eyes of academic colleagues and the wider public is the cornerstone of a successful career for a neurologist in industry. Loss of credibility in the corporate environment, although not morally different than elsewhere, is far more likely to have disastrous consequences, as losing the trust of academic peers will inevitably restrict one's employability.

Hiring Process

All pharmaceutical companies have career tabs on their websites where one can apply for specific positions or submit a resume. These instruments are not an ideal forum for a qualified physician–scientist, as the recipient is often anonymous, and the distribution of the information remains unknown. If a specific position on a website looks interesting, a good alternative to an online application is to find out which recruiting agency has been retained for the search, and to gain more information through them. In many instances, potential candidates are contacted by a recruiter or agency for a specific position on behalf of a pharmaceutical company. Our advice is always to take such agency's calls, even when a specific position does not look interesting on the surface. Establishing a personal contact with recruiters can provide highly valuable insights into how the system works and may reveal additional job opportunities now or later. Recruiters are anxious to gain the trust of candidates and therefore handle personal confidential information with discretion. As a novice, it is helpful to discuss a job opportunity with colleagues who both in industry and in academia to highlight the perspectives from different angles. Both the recruiter and colleagues in industry can introduce an academic candidate to the semantics of job titles, specific responsibilities implied and stated, and organizational structures whose understanding is necessary to properly vet an opening.

Outlook

We predict that the need of the pharmaceutical industry for neurologists who are qualified both as clinicians and as scientists will continue to increase, based on the premise that scientific progress will make more currently unmet medical needs accessible to therapeutic intervention. The pharmaceutical industry itself will undergo important structural changes in the coming years, mainly driven by economic pressures. Those corporate entities best at translating scientific breakthroughs into novel and effective therapies will be the most successful. The ongoing concentration process, with the absorption of small (ie, biotech) and intermediate companies by large pharmaceutical companies will likely be superseded by increasing specialization, a process by which each company will likely focus its activities on selected disease areas of expertise to maintain a competitive advantage. The consequence of this evolution is that a neurologist who considers a career in the corporate sector must evaluate not only the scientific potential of a specific firm but also issues such as the company's dedication to unmet clinical needs, financial stability, resilience in the development process, and managerial flexibility, all factors that that contribute to corporate success.

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