A relatively unknown fact in our industry is that all of the nearly 25,000 marketed drugs today have evolved from modulation of just 324 molecular targets (J.P. Overington, Nature Reviews Drug Discovery). This statistic implies that much of the progress in patient care is the result of improvements to existing drugs, and not from advances against a novel disease target or mechanism of action. To address the challenges in industry productivity, companies have begun to apply two distinct drug discovery and development strategies.

For big pharma, blockbuster drugs of the past may no longer meet their commercial hurdles because they risk not meeting payer reimbursement and medical society care pathway guidelines. The path to meeting those hurdles requires expensive health outcomes research fraught with risk and extended development timelines. With costly investments in new genetic sequencing and data mining technologies, they instead focus their budgets on novel mechanisms of action, including rare or orphan diseases, which either ensure a market position with no comparators or where pricing is defensible based on proprietary status and smaller patient populations.

At the other end of the development continuum are companies focused on advancing compounds using a 505(b)(2) regulatory strategy. Applying this strategy, a product may have the same active ingredient as a previously approved product, but is formulated in a different delivery system or is developed for a different indication. This approach lowers risk because the applicant can rely on studies from the original drug and simply demonstrate efficacy and safety with the new dose form or in the new area of use. The superiority of the new delivery form drives prescribing from the older drug to the newer drug, which is allowed a limited patent-protected exclusivity position. Examples range from the development of thalidomide in cancer by Celgene to Pfizer’s Zyrtec D decongestant formulation as a line extension of their blockbuster antihistamine.

What’s missing in this bifurcated mix is the development of drugs from first-in-class to best-in-class. Indeed, over the last 50 years, this strategic approach has played a major role in moving care forward, and represents the place where the industry has classically generated its greatest share of revenues and profits, as evidenced by several recent deals and
collaborations. Simply put, “the most fruitful basis for the development of a new drug is to start with an old drug.” (Sir James Black, Nobel prize-winning Scottish doctor and pharmacologist who discovered beta-blockers and H2 antagonists.)

Today, the probability of a new drug project reaching preclinical development is only 3% for novel targets (Accenture and CMR). In contrast, historical data show that follow-on drugs are inherently less risky with about 1 in 123 making it to market, a rate almost double that of drugs based on novel approaches (McKinsey). Further, over the past 20 years, the highest value has come from drugs that entered the market two to five years after a comparable novel one. Pfizer’s Lipitor was the highest revenue grossing drug of all time, a successor from statins that began with Merck’s Mevacor and Zocor.

At SciFluor Life Sciences, our business model is predicated on the skills and experience of our scientists to discover new drugs using fluorine atoms to enhance the profiles of clinical compounds and reduce the liabilities of currently approved drugs. To ensure the value of the “best-in-class” strategy, we develop target product profiles and set goals around pharmacokinetic properties, in vitro and in vivo data compared to the marketed drug, side effect and dosing profile, and other key attributes that will define the profile for commercial acceptance.

If these hurdles are not met, we stop further development and move on to the next project. In doing so, to the degree possible at these early stages, we are assured that our best-in-class compounds will not be considered “me-too” agents, and that our chemistry advances will demonstrate the necessary health outcomes improvements to ensure commercial viability.

Just as any financial planner stresses portfolio diversification as the best strategy to balance risk and reward, companies have the ability to build a diversified portfolio of projects that balance both novel approaches and incremental improvements to demonstrate innovation and value. We need to balance the allure of discovering novel molecular pathways and Wall Street’s desire for short-term revenues with the lower risk and achievability of new best-in-class agents that can help achieve the goals of lowering health-related costs, while also enhancing the quality of patient care.

Isn’t it time your law firm focused on what matters to you?

You need to execute a strategy that will build value and sustain the health of your business. Our attorneys have the experience, resources, and know-how to help you navigate industry-specific challenges and obstacles to meet your goals. Since the birth of the life sciences industry in the 1970s, we’ve helped individuals and companies with their transactional, regulatory, and intellectual property matters. Your success is our success.