TrumpCare: The Pharmaceutical Industry and FDA

Buchanan Ingersoll & Rooney PC

The first in a series of articles to help you deal with legislative and regulatory issues as President Trump and a new congress take hold.

Hope in the Midst of Uncertainty

The New Year ushered a period of uncertainty for the pharmaceutical industry. We face the beginning of the Trump Administration and a Congress with both houses controlled by Republicans focused on repealing Obamacare. The financial cost of this repeal could be significant to the healthcare industry. This change, combined with President Trump's economic nationalism and attacks on drug pricing, create an atmosphere of doubt and uncertainty for the pharmaceutical industry. Additional complicating factors include the expiration of the Prescription Drug User Fee Act and the Generic Drug User Fee Act in September of this year. The fees generated by these pieces of legislation contribute to the majority of the revenue supporting the drug approval process. Legislative replacements will need to be enacted to ensure the status quo or improvement to the current rate of NDA and ANDA approvals. For the past 25 years, Congress sought to pass clean User Fee bills. That has never happened and is unlikely to happen this year.

The future is not necessarily bleak. 2016 had the lowest number of new chemical entity approvals since 2007 but, taken as a whole, FDA has been approving new chemical entities at an extraordinary pace. According to CDER's Novel Drugs Summary for 2015, 87% of new chemical entities were approved within one cycle of review. Adding to that momentum, Congress recently enacted the 21st Century Cures Act to improve and fund the new drug review and approval process. The pharmaceutical industry has enjoyed excellent growth in sales volume, independent of price increases. Private payers, pharmacy benefits managers, and distributors are playing increasingly powerful roles. Many promising, new and costly therapies are on the horizon. However, the continued uncertainty as to the new administration's priorities may trigger caution by investors rather than renewed interest in research and development to spur innovation.

Without any change in the political environment, concerns arose regarding drug pricing, which were exacerbated by incendiary social media commentary. The enduring nature of the drug pricing debate was magnified due to extensive changes in the healthcare system, especially in the private sector. Additionally, almost half of the top 20-selling drug products are biologics that are used under Parts A and B of Medicare rather than as outpatient drugs. Adding to the equation, the incoming Administration and Congressional leadership have signaled that tax reform will be a priority. At this time, the focus is on reducing and simplifying corporate and individual rate structures. Another focus will be encouraging the repatriation of money being held off-shore by American tax-domiciled companies. As with all major reforms there will be winners and losers because there will be at least some pressure to ensure that the reforms are budget-neutral. In these situations, the pharmaceutical and health care industries have historically provided approximately one-third of the necessary increased revenue.

Uncertainty and change are upon us. Just as Brexit has caused uncertainty and unintended consequences, our goal is to address issues emerging as a consequence of Washington's actions through a series of thought-provoking pieces.

Where It All Started

Russell Long, the former Senator from Louisiana and Chairman of the Senate Finance Committee, supervised the enactment of the Medicare and Medicaid legislation in 1965. He viewed these seminal pieces of legislation as a covenant between the Federal Government, the States and the private sector. The Federal government would provide care for the elderly, the states would provide care for the poor, and the private sector would provide coverage for the working public. Initially Medicare only covered the costs for in-patient hospital care and treatment by physicians. This program is Part A of Medicare. Non-self-administered drugs for the elderly, such as oncology agents, are covered

by Part B of Medicare. The states have historically provided outpatient drug coverage, and the private sector gradually provided outpatient coverage. Not every state initially bought into the Medicaid program. However over half of states implemented a Medicaid program within the first year federal funding became available, and nearly all states were participating in Medicaid within four years.

Congress enacted the Medicare Catastrophic Care Act in 1988 to provide outpatient drug benefits to the elderly and to protect older Americans from bankruptcy due to medical bills. That provision was later repealed as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) due to an outcry of wealthy elderly citizen arguing that they were paying a disproportionate share of the benefit. OBRA '90, however, established the Medicaid drug rebate program, which requires every participating company to provide a rebate for every product, pioneer or generic, to the states for participation in the program. For innovator products, the rebate is based on the lowest price (a "Best Price") for which the drug is sold in the United States. For Generics, the price is based on the Average Manufacturing Price. The rebate percentages continue to rise as Congress seeks additional money from the industry to cover budget deficits. It took almost 15 years for the return of outpatient benefits through the Medicare Modernization Act in 2003. This framework remains in effect today, and proposed changes should be viewed within this construct. According to the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), the total sales of pharmaceuticals in the United States were $457 billion in 2015. The sales of outpatient drugs are reported to be $340-350 billion. According to the US Government Accountability Office (GAO), the sales of physician administered drugs, Part B, of Medicare were $21 billion in 2014, the most recent year for which data were available. Hospital sales, including in Part A, and other Parts constitute about $80-100 billion.

Drug Pricing: Tweets, Transparency and Taxes

Drug pricing has become a lightning rod issue for this new Administration. Trump routinely tweets about the issue in general, and his current pattern is to ultimately single out a company and perhaps individuals in that company. Members of Congress are hearing from constituents complaining about drug prices, and regardless of political party, all are concerned. Republicans have placed the onus for high prices on FDA, alleging that delays in the generic and pioneer approval processes foster a lack of competition. Conversely, Democrats have focused on pharma industry greed, seeking caps on drug pricing, government negotiation of prices for Medicare and Medicaid, and the authorization to import drugs. These historic arguments have failed to generate any consensus. In fact they all seem stale. None have the bravado that characterizes Trump and his potential goals for "TrumpCare." Despite the public outcry over Turing Pharmaceuticals' price increase for Daraprim, the price of the drug remains unchanged one year later. This may be partially because Turing, unlike Mylan, is privately owned.

Most new concepts will require legislative action, but in the current climate with the repeal of Obamacare, the need for user fees, and tax reform heating up, new ideas may gain traction. The least controversial change will be a focus on transparency. Unlike most industries, purchasing mechanisms in healthcare and pharmaceuticals are often opaque. Multiple parties exist between pharmaceutical companies that sell drugs and the consumers who ultimately purchase them. Exposure and discussion of the roles of pharmacy benefit managers, distributors, private payers, and others in the middle will draw increased scrutiny in the coming year.

The new administration is likely to use the tax system to draw concessions from corporations. Numerous companies have drawn public scorn for their skillful navigation of the US tax system over the past few years. Many of these companies have taken advantage of tax mechanisms such as inversions to relocate their legal domicile to a tax-advantaged nation while maintaining their US operations. Most of these nations have legislation in place that require the sale of pharmaceuticals at prices vastly inferior to the US market. One potential avenue of reform could mandate a Best Price calculation for Medicaid rebates that is based on the price of pharmaceuticals in the company's tax domicile. This type of approach would conform to Trump's oft-repeated economic nationalism agenda to encourage the repatriation of US companies and manufacturing from foreign countries.

Increasing competition and CandorExpediting the approval of generic drugs is viewed by some as perhaps the best way to reduce drug and healthcare costs. For the past

decade, the number of ANDAs filed has significantly increased. FDA has been unable to reduce the backlog, even with ever-increasing user fees. FDA has traditionally treated information about the queue as confidential commercial information. This treatment is a vestige of the generic drug industry's early stages in the 1970's as a group of small, closely-held domestic corporations that competed with one another discretely. Each company developed products in private from the vast array of drug products approved prior to 1962, solely on the basis of safety that were subsequently found to be effective under the Drug Efficacy Study Implementation (DESI) as the target list of what are now called Reference Listed Drugs (RLD).

The passage of the Hatch-Waxman Act in 1984 led to the creation of the Approved Drug Products with Therapeutic Equivalence Evaluations list, commonly known as the Orange Book, as the statutorily recognized source of RLDs. Pre-approval patent litigation was created as the norm to bolster the generic industry and increase public access to low-cost alternatives. Generic companies became publicly traded and multinational. Litigation is public in most aspects and provides information about the queue to other companies involved in competitive litigation. Today, no one treats this information as confidential commercial information except FDA. Legislation that forces (or permits) FDA to reveal all Paragraph IV litigation, the number of ANDAs filed for each RLD, the dates of the filings and other information would permit generic companies to invest their research and litigation dollars more intelligently and reduce unnecessary filings. It would also identify opportunities where little or no generic competition exists that will drive competition and lower drug prices. Frequent interactions and dialogue between FDA and drug applicants have led to a high percentage of first cycle approval for NDAs. The sheer volume of ANDAs makes replicating that process today difficult, but it should be considered, especially for the generic equivalent of breakthrough products - ANDAs where the RLD lacks competition.

Other steps FDA, under a Trump administration, may take to reduce the queue without increasing user fees could involve creating abbreviated ANDAs with only limited Pharmaceutical Quality/CMC sections for drug products that have numerous existing ANDAs. Does FDA really need to review the bioequivalence data for an immediate release ibuprofen, after 30 + years of generics? FDA proposed to make that product a monographed drug in the 1990s but never finalized its proposal. With scores of drug products sold as OTC after RX-OTC switches via ANDAs, must the Office of Generic Drugs waste resources reviewing the bioavailability data for these drug products as well as monitor their pharmacovigilance?

Correspondence between applicants for NDAs and the reviewing divisions has also historically been considered confidential commercial information by FDA. As the rate and number of NDA approvals has increased, pressure has mounted on publicly-traded companies to obtain approvals. Treating FDA as the scapegoat is a time-honored tradition. FDA has been called a large slow-moving target that bleeds easily and profusely. But the practice seems to have gone beyond the pale. The recently retired head of FDA's Office of New Drug Evaluation complained that a number of companies have been inaccurate, if not intentionally misleading, about the contents of their Complete Response Letters. FDA and SEC previously announced that they are partnering to ensure that investors are not mislead about FDA actions, but perhaps FDA needs greater statutory authority. As public markets often provide the financing for emerging companies, legislation that authorizes FDA to routinely release CRLs or to release them if a dispute arises, makes eminent sense. FDA now routinely makes Forms 483, related to the manufacturing of drug products that may not be approved, publicly available. Companies have their rebuttals listed as well so that the dialogue becomes public. Further, There is no reason for a difference in the legal status of NDA correspondence and ANDA correspondence.

Our next article will focus on the potential impact of TrumpCare on regenerative medicine.

Authored by:

Edward Allera and Linda Pissott Reig, Co-Chairs of Buchanan Ingersoll & Rooney's FDA practice with the assistance of Alexandre Gapihan

Learn more about the FDA practice at **www.BIPC.com/FDA**