The United States Pharmaceutical Industry – Paying More Than Its Fair Share

The US pharmaceutical industry has endured both public scrutiny and financial challenges in recent years. Under the newly passed Patient Protection and Affordable Care Act (PPACA), the industry is preparing to shoulder an even larger financial burden. The PPACA and other trends driven by the federal government are creating a very challenging environment for pharmaceutical manufacturers. Higher taxation, expanding regulation, and an increased number of federal investigations, for example, have all recently emerged. Increased federal mandates via legislation create new and unique challenges which the industry has not encountered in recent history: declining revenues/resources coupled with increased expenses/federal mandates. Subsequently, there have been declines in headcount across the industry, smaller margins, poor stock performance, wage freezes, and other associated collateral damage that occurs within an industry in decline.

Background

The average life expectancy in the United States is trending to 79 years of age, which is 12% longer than the average lifespan of 70 years in 1965.[1] This is the same year Lyndon Johnson, as part of his "Great Society", signed the Social Security Act which created the Medicare and Medicaid programs. Since that time, Medicare has been vastly expanded to include disabled persons under age 65 and end-stage renal disease sufferers. It also covers hospice benefits, routine mammography, pap smears, and, starting in 2003, prescription drugs via the Medicare Modernization Act. In 1965 there were 18 million people over the age of 65 (with an average life expectancy of 5 years remaining). In 2010 there are more than double that amount — 37 million people with an average life expectancy of 14 years remaining. Hence, multiplying the US population over age 65 by the average life expectancy remaining demonstrates an important and staggering change in treatment load. Compared with remaining patient-years to treat at the time of agency inception in 1965, the Medicare program as of 2010 has experienced an almost six-

[1] Data source: World Bank, World Development Indicators. Updated June 15, 2010.

fold increase in remaining patient-years to treat. Furthermore, Medicare must at the same time cover a much broader array of services and treatments. It is no surprise that prior to PPACA, the Medicare Trust Fund projected fiscal exhaustion in 2017.[2]

Medicare Funding

The hospital portion of Medicare maintains a separate trust fund and is resourced via payroll taxes totaling 2.9% (a 1.45% employee tax is then matched by employers as part of FICA). Total income for 2008 was $231 billion versus total expenditures of $236 billion,[3] a net loss of close to $5 billion — or roughly 2%.

The Supplementary Medical Insurance (SMI) Trust Fund handles all other parts of Medicare outside of the hospital, including Medicare Part B and Medicare Part D. Income for the SMI Fund is transferred from the General Treasury to create about three quarters of its financial sourcing, with the remaining quarter sourced via patient premiums.

Pharmaceutical Industry Trends

It is reported by the global outplacement firm of Challenger, Gray, and Christmas that the pharmaceutical industry is second in job layoffs only to the non-profit government sector, with over 80,000 total jobs cut from 2009 through the first half of 2010. This can be attributed to a variety of reasons such as shrinking pipelines, patent expirations, and the overall suffering economy. As a result, it certainly has not become any easier for the industry to abide by the numerous regulations and incremental taxes that have applied additional pressure to financial performance.

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[2] A Summary of the 2009 Annual Social Security and Medicare Trust Fund Reports. Available at: www.ssa.gov. Accessed Month XX, 2010.

[3] 2009 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Available at: www.ssa.gov. Accessed Month XX, 2010.

Federal Regulation and Mandates

First, the Sarbanes-Oxley Act created additional reporting burdens for all companies in 2002. While noble in its cause following several corporate and accounting scandals such as Enron, debate still exists as to the benefit of the Act versus the costs associated with compliance to its mandates. Next, and more impactful, the Health and Human Services (HHS) Office of the Inspector General (OIG) issued thorough and complete guidance to pharmaceutical manufacturers, outlining all necessary steps in order to achieve promotional compliance. Again, the guidance is noble in its cause; however, it intensified the burden of additional tasks and oversight responsibility. Compliance programs are typically labor-intensive, thus creating further financial pressures upon pharmaceutical companies. Lastly, there has been an astounding increase in the number of investigations and prosecutions related to pharmaceutical manufacturer sales and marketing practices. These actions have led to record financial settlement amounts — totaling close to $5 billion — related to off-label promotions in just the past two years.[4] Finally, PPACA is responsible for additional reporting measures such as the Physician Payment Sunshine Act, which mandates tracking and reporting of all payments made to physicians by manufacturers.

OIG Investigations and Settlements

The OIG often negotiates compliance obligations with health care providers and other entities as part of the settlement of federal health care program investigations arising under a variety of civil false claims statutes. A provider or entity consents to these obligations as part of the civil settlement, and in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other federal health care programs.[5] Thus, pharmaceutical companies rarely if ever go to trial to defend against allegations of impropriety, since the impact of losing such a defense in court could lead to being placed on

[4] DOJ Settlements of Cephalon, Inc. (2008), Eli Lilly and Company (2009), Pfizer, Inc. (2009), AstraZeneca Pharmaceuticals L.P. (2010), Ortho-McNeil-Janssen Pharmaceuticals, Inc. (2010).

[5] Data on file. Available at: http://oig.hhs.gov/fraud/cias.asp. Accessed Month XX, 2010.

the Federal Exclusion List. Obviously, the financial impact of being excluded from participation in federal programs could be enough to put a company out of business.

The trade group Pharmaceutical Research and Manufacturers of America (PhRMA) represents 29 brand manufacturers which compose roughly 80% of branded product sales. Of those 29 companies, over 50% are currently under a Corporate Integrity Agreement (CIA) or under a publicly disclosed active investigation. There may be more even more undisclosed investigations, which are typically not publicized until a company under investigation is obligated to make an announcement.

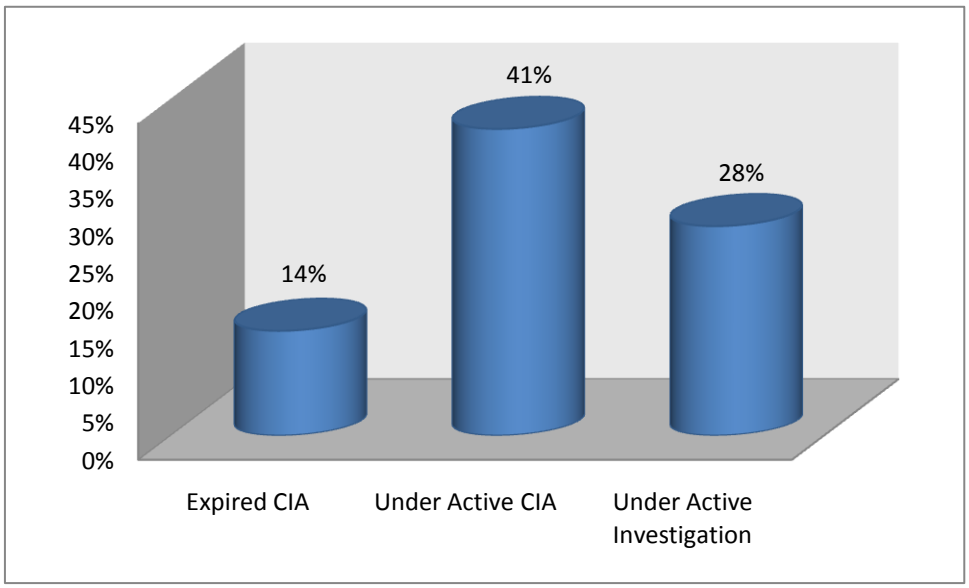

Figure 1.Percentage of PhRMA Companies under expired CIA, under active CIA, or under publicly disclosed active investigation.[6]

PPACA

Within PPACA there is a mandate for an incremental tax on the sale of branded pharmaceuticals. It is a somewhat convoluted calculation, and will average close to $3 billion annually over the next 10 years.[7] Furthermore, PPACA raises the minimum Medicaid rebate from 15.1% to 23.1% (a >50% increase) and also expands the number of entities who qualify for 340B pricing, which

[6] Analysis of PhRMA companies. Available at: www.phrma.com. Accessed Month XX, 2010; Analysis of CIAs. Available at www.oig.hhs.gov. Accessed Month XX, 2010.
[7] US Congress. Patient Protection and Affordable Care Act, Section 9008; 2010.

is at least as low as the Medicaid price. Once again, downward financial pressure on the industry is further intensified by this policy.

Interestingly, according to a memo from the Chief Actuary Richard S. Foster at the Centers for Medicare & Medicaid Services (CMS), "The revenues from fees on manufacturers and importers of brand-name prescription drugs under Section 9008 of the PPACA are earmarked for the Part B account in the Medicare Supplementary Medical Insurance trust fund."[8] As stated earlier, this trust fund is sourced primarily from the General Treasury. Hence, from the standpoint of the federal budget, these amounts are new receipts and serve to reduce the budget deficit. Furthermore, according to Foster, "With no change to existing financing, the additional revenues under Section 9008 would result in an excessive level of financing for Part B and an unnecessary accumulation of account assets."[9] In other words, it appears based upon this actuarial report that the taxes collected from branded pharmaceutical manufacturers will simply be used at the President's discretion, or to reduce the deficit. A simple question arises: How is that fair? Since we are not allocating the $3 billion in incremental taxes paid by the pharmaceutical industry to directly offset patient drug costs, why are other industries not being incrementally taxed as well?

Conclusion

Through innovation the pharmaceutical industry has improved the lives of millions of Americans. The industry has been at the forefront of advances in science and technology to formulate medicines which improve patient outcomes in all disease states. Inarguably, Americans have benefitted greatly with improvements in quality of life due to these efforts. Clearly, pharmaceutical advancements have been responsible for reducing total health care costs by reducing hospital stays and surgeries. Further governmental regulation and taxation seems to only stifle future growth and innovation.

It is illogical to think that the pharmaceutical industry can continue to create and develop new medicines at the same rate shown in the recent past. Already we have seen fairly dramatic

[8] "Estimated Financial Effect of the Patient Protection and Affordable Care Act", Richard S. Foster, CMS Chief Actuary. April 22, 2010.
[9] "Estimated Financial Effect of the Patient Protection and Affordable Care Act", Richard S. Foster, CMS Chief Actuary. April 22, 2010.

reductions in the size of the pharmaceutical workforce. One must consider the strong possibility of this trend continuing, based upon the numerous upcoming industry challenges outlined above.

It does not seem to be prudent, appropriate, or in the best interest of Americans to tax and regulate ourselves out of another thriving industry, let alone negatively impact the health and well-being of future generations.

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