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Is Biopharmaceutical Industry Drug Demand Becoming More Recession Sensitive?

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> No one saw the **recession** coming.
>
> *Gordon James Ramsay, OBE Chef, restaurateur, television personality*

> What we know about the **global financial crisis** is that we don't know very much.
>
> *Paul A. Samuelson*
>
> *Nobel Prize-winning economist*

Introduction

The Great Recession in the U.S. began in December 2007 and ended in June 2009 according to the National Bureau of Economic Research (NBER) Business Cycle Dating Committee, the organization that officially determines the chronology of the U.S. business cycle. Given the increasing economic trade and financial interdependencies between countries in the global arena, the financial meltdown contagion spread from the U.S. to become a global recession. This economic period marked the longest and by many measures the largest economic downturn since The Great Depression of the 1930's. The effects of The Great Recession were made more pronounced given its global nature and breadth of impacts across many sectors of the domestic and world economies. This white paper will focus on learning about The Great Recession and its relationship to biopharma industry drug demand. In particular, three questions will be explored about the future relationship of economic recessions to biopharma drug demand given evolving industry market and environmental trends:

1. Is biopharma industry drug demand becoming more recession sensitive? If "yes", why and how?
2. What role does commercial analytics have in allowing biopharma companies to mitigate the potential adverse effects of recession-induced demand effects on business operations?
3. What does the future hold on the impact of the next severe recession on biopharma industry drug demand?

Is biopharma industry drug demand becoming more recession sensitive?

The "urban legend" about the sensitivity of biopharma industry drug demand to the business cycle prior to The Great Recession was either that it's recession-proof or recession-resistant. The latter phrase is simply to recognize a potential slight difference in the elasticity effect of percentage changes in drug demand to percentage changes in national GDP (gross domestic product). Yet surprisingly, very little publicly available empirical research exists on this topic specific to the drug industry, though it is very possible internal proprietary research was done by biopharma companies as evidence of the severity of the recession became more apparent. What does available academic research suggest on this topic? A December 2011 survey study concluded that the recession did not cause an increase in difficulty for people to access

prescription drugs.[1] A November 2012 empirical study looked at the association of state-level unemployment rates with drug utilization across seven therapeutic classes from September 2007 to July 2010.[2] No statistically significant associations were found for the use of ACE inhibitors or SSRIs/SNRIs, while small statistically significant direct associations were found for opioids and PDE inhibitors.[2] Negative associations were found for statins, antipsychotics, and oral contraceptives.[2] Methodological issues with this analysis call into question the robustness of the findings. For example, there is concern over the state-level aggregate nature of the analysis (instead of looking at a finer geographic local unit area such as a metropolitan statistical area), therapy class utilization was analyzed (instead of analyzing individual drug demand), and using only the unemployment rate represents only one aspect of the effect of measuring a recession (instead of utilizing numerous measures to account for different effects of recessions). A recent September 2016 study noted that the period from 2005-2013 saw US prescription drug market spending as measured by IMS Health grew at an annual rate of 1.8%.[3] A number of factors beyond the effect of The Great Recession could have been at play here, such as the growth of patent expirations and the rise of spending on lower-cost generics and increased influences from pharmacy benefit managers and health insurers to reduce spending on prescription drugs or greater cost-shifting to patients that will reduce drug utilization.[3] An analysis reported in November 2015 affirmed the above factors beyond The Great Recession in causing health care spending to decline.[4] However, the shift to generic drugs caused by patent expirations, shifted drug utilization from branded to generic drugs, thereby improving adherence and improving health outcomes, thus would also contribute to reduced non-prescription drug spending (e.g., hospitalization and physician spending).[4] A similar type of finding was found looking at the increased use of generic drugs during The Great Recession that produced health care spending savings.[5] A March 2015 blog noted that while some effect of the downturn in health care spending in the 2009-2013 period was due to the lingering effects of The Great Recession,

the reduction of economy-wide inflation represented the biggest factor affecting post-recession spending.[6] Lastly, it was reported in 2010 that the recession was causing cancer patients to discontinue life-extending drug therapy due to cost caused by the inability of patients to afford insurance to cover the expense.[7] This last note is important given the increasing focus of biopharma company R&D and US spending on medicines being increasingly driven by specialty medicines, and especially from very expensive new cancer drugs. The effects of the next severe recession could very well have similar consequences facing patients having to afford expensive medicines if affordable insurance is unavailable. Thus, while there is an overall dearth of empirical evidence connecting the sensitivity of biopharma industry drug demand to a recession, there are reasons to be believe such effects are likely to be stronger the next time a severe recession strikes again.

What then are the mechanisms by which a severe economic downturn, like the one experienced in The Great Recession, would have on explaining effects on biopharma industry drug demand? Using economic theory, a severe recession would have effects on drug demand via four mechanisms:

1. **Disposable income effect** - A reduction in real (inflation-adjusted) disposable income caused by falling or stagnate wages, making the affordability of branded drugs medicines more difficult.

2. **Unemployment / labor force participation / loss of insurance effect** - Higher unemployment which results in a loss of patient health/drug insurance provided by employers. Generally speaking, unemployed individuals can extend health insurance in most cases for 18 months though COBRA (Consolidated Omnibus Budget Reconciliation Act of 1985) post-termination, but employees pay for the full cost of the monthly health premium (employer plus employee premiums) plus a 2% service charge. The cost of COBRA insurance coverage may be beyond the means for people who are already financially strained given their loss of employment and

the effects of a recession, thus may choose to drop coverage. A broader and better measure of labor market health would be the labor force participation rate, the number of people who are employed and unemployed but actively looking for a job divided by the total number of eligible workers between the ages of 16-64. Since The Great Recession, this rate has diminished and flattened out to a rate just below 63%, a rate not seen since the late 1970's. The passing of the Affordable Care Act and the availability of insurance through exchanges not connected to employment and subsidization of premiums based on income may mitigate the effects from poor labor market health and declining access to employer-provided health insurance.

3. **Wealth effect** - A severe recession may reduce the value of financial and physical assets, e.g., respectively, changes in the value of equities and bonds versus changes in assets like the price of housing. People who are in or close to retirement may use these assets for future spending, thereby reducing drug affordability similar to a disposable income effect.

4. **Government effect** – A recession depresses tax revenues, which means government-provided health insurance like Medicaid for the poor may become more restrictive in their drug benefits, especially in the demand for branded drugs, and/or shift drug demand to generic drugs through typical managed care control mechanisms.

The above four effects would make their impact seen on pharma drug demand in the following ways since a severe recession produces varying consequences on different segments of the population based on their relationship to the economy, e.g., a rising unemployment rate has little effect on drug demand for therapy classes dominated by patients who are elderly retired individuals:

- Lower utilization of patented branded drugs, with greater sensitivity seen for more expensive specialty medicines (which should exhibit greater price and income elasticities).
- Greater utilization of generic drugs as an inexpensive substitute of the original molecule branded drug. This means a severe recession will trigger greater/faster bioequivalent and therapeutic brand to generic substitution.
- Lower utilization of drugs in therapy classes where patients must absorb a proportionally greater out-of-pocket expense.
- Lower drug compliance (the filling of a prescription received from a physician) and adherence (how patients take their medications). Lower drug adherence can be observed by patients, for example, skipping their daily medication usage spread over two days, pill splitting if pricing per mg dosage does not vary (e.g., patients buying a 20 mg of pills and splitting them into 10 mg pills).
- Greater utilization of mail order relative to retail pharmacy as a channel to receive medications at a lower cost.
- Greater demand for samples from physicians, especially in geographic areas or population segments that are more sensitive to changes in economic conditions.
- Patients with multiple conditions in difficult economic straits will more likely choose continuing drug therapy for symptomatic conditions over asymptomatic ones. Thus, for example, older individuals who have osteoarthritis, diabetes, and hypertension will more likely choose continuing their osteoarthritis medication over the latter conditions, even though controlling their diabetes and hypertension is likely more medically important. Therefore, a recession is likely to cause patients to make suboptimal healthcare choices.
- Greater movement by patients into catastrophic higher deductible health/drug plans since they are less expensive, but will also translate into receiving less healthcare/medications given the higher out-of-pocket expense. Less access to healthcare/drugs will have adverse consequences on health outcomes and overall medical care spending.
- Greater geographic variations in drug demand utilization seen around the country as the recession could generate different local and regional effects. For example, during The Great Recession, specific cities and regions were severely

impacted that relied more on heavy manufacturing and auto production (like Detroit and "rust-belt" states) for their economic base, or areas severely affected by the housing collapse like Las Vegas, California, and Florida. Greater drug demand effects would be seen in local areas and regional economies that were less economically diversified and more susceptible to any one change in a recession index.

Role of commercial analytics to mitigate recession-induced drug demand effects

What role should company commercial analytics have to mitigate recession-induced drug demand effects? One may be tempted to respond by saying that a response would be quite limited since individual companies cannot affect the course of domestic or global macroeconomic trends. This would be a mistake. There is a wealth of historical economic data that exists at the local (e.g., city and metropolitan area) or regional (e.g., state) levels. Furthermore, business and economic organizations project forward trends in the types of measures that would trigger recession-induced drug demand effects as earlier explained. Together, econometric inference models could be developed at the local/regional levels to determine the extent of drug demand effects from changes in specific economic factors relative to company management control and market-oriented variables (e.g., sales, marketing, market access). Empirical results would reveal variations by geography in these relative effects given the wide diversity of economic conditions around the country. Furthermore, results from inference models could then be used to estimate future drug demand effects based on projections of economic activity and assumptions on company management control variables going forward.

There are numerous potential business insights gained from the previously-stated research path of applying commercial analytics to economic and non-economic data on drug demand (non-exhaustive list):

- The results may reveal surprising insights, that economic trends play a much more significant role in affecting drug demand relative to management control variables than first thought. Given the growing trend toward launching expensive specialty medicines, the structure of economic variables is likely to play an even greater impact on drug demand relative to traditional sales and marketing channels. Marginal, elasticity, and relative importance (standardized coefficients) estimates could be derived from a wide range of drug demand models.
- A company can position commercial resources differently by local area according to economic dynamics. Local/regional differences in economic effects may suggest variations in managed care contracting, access to coupons, demonstration of greater drug value through promoting disease management programs, differentials in drug messaging through personal/non-personal/consumer promotion channels, etc. are all possible as a result.
- National, regional, and key local area company financial forecast accuracy could be improved by introducing the effects from economic variables. This means these models could determine the extent of any drag on financial forecasts from recessionary effects.
- Models could be used to determine not only specific drug demand by prescription type but also by payer channel and brand to generic substitution ratios. One would expect as a recession becomes more severe and lasts longer, forecasts could be developed to see how many prescriptions move from 3rd party commercial to Medicaid. Changes in Patient Assistance Program (PAP) enrollment figures could be forecasted due to worsening economic conditions.
- Anonymized patient level data (APLD) models could be developed to determine changes in drug adherence due to worsening economic conditions.

The main point of the preceding bullets is that a company could be much more aware of the full extent of impacts caused by a severe recession and take management control steps to mitigate adverse effects.

How will the next severe recession affect biopharma industry drug demand?

The point of the opening two quotes is simply that despite the best attempts by economists to understand the causes of the business cycle, our ability to predict the next financial collapse and subsequent recession is no closer after The Great Recession than before. As Edgar R. Fielder noted in a famous quote, "He who lives by the crystal ball soon learns to eat ground glass." Macroeconomists have been feasting on ground glass before, during, and after The Great Recession! So, for biopharma companies to think they can do better is not likely to happen. So the best biopharma companies can expect to do is have systems and commercial analytics in place to monitor changes in macroeconomic conditions and be prepared to initiate business policies as a result of movements toward a recession. The growing industry shift to specialty medicines introduces a greater inherent risk to companies from the next recession, even one of equal or less severity than The Great Recession. The result will likely produce even bigger adverse effects. In short, biopharma drug demand will become more recession sensitive as the biopharma market structure shifts toward specialty medicines with a severe recession intensifying growing issues over affordability by individuals, economic pressures placed on commercial, government reimbursement systems, and employers to pay for covering more expensive medicines. A key mitigating factor is for companies to put in place systems and capabilities in commercial analytics to better understand how changes in the business cycle affect drug demand and related measures, and its impact on changes in business policy.

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