COVID-19 Recession Effects on Pharmaceutical-Related Patient Health Outcomes

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EXECUTIVE SUMMARY

The COVID-19 outbreak, along with the associated business closures and social distancing mandates, has created the worst economic recession since the Great Depression. This depressed economic environment will not only cause a decrease in branded/biologic drug utilization but also a decline in patient health outcomes. This white paper investigates these relationships in the following manner:

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Given the dynamic nature of this pandemic, please subscribe to the *Axtria Research Hub* (https://www.axtria.com/axtria-research-hub-pharmaceutical-industry/) for updates to this white paper and related postings.

> The Great Lockdown. The world economy will experience the worst recession since the Great Depression.
>
> **Excerpt from the International Monetary Fund, *World Economic Outlook*, April 2020[1]**

1. A Severe Global and US Recession is Here

1.1 The "Great Lockdown"

We are now in the midst of the most significant and deepest global recession since the Great Depression, as noted in the above quote and recently announced by the International Monetary Fund (IMF). The projected economic collapse will dwarf in severity what occurred during the Global Financial Crisis of 2007-2009 and the associated US Great Recession during the same period, according to the IMF report. The advanced economies of the US, Euro area, Japan, United Kingdom, Canada, and other countries in this category will see an average group annual percentage change in the real gross domestic product (GDP) for 2020 of -6.1%.[1] Italy (-9.1%), Spain (-8.0%), and the US (-5.9%) will have significant projected annual declines in 2020 real GDP in line with the severity of the COVID-19 outbreak per country per capita.[1]

The future economic situation in the US is especially bleak. Weekly jobless claims over the last nine weeks, since the outbreak and shutdowns have occurred, ending on May 15, 2020 have totaled 38.6 million people.[2] This job claims figure relative to a total labor force of 162 million, translates into an estimated national unemployment rate of 23.8%.[2] This rate greatly exceeds the official April 2020 figure of 14.7%, is vastly higher than any rate seen since the Great Depression, and unfortunately, even members of the Trump administration's economic team expect this rate to go even higher before we start seeing a recovery. The worst year of the Great Depression for unemployment was 24.9% in 1933. It is very possible the US could exceed this rate given the economic effects of state lockdown orders and the closure of non-essential businesses. Federal Reserve Chairman Jerome Powell recently indicated a full economic recovery is not likely until a vaccine is found. Recent reports have illustrated the longer-term transformative effects of this recession, such as, the bankruptcy filings of many iconic-named stores. About 25% of restaurants that have been shut down through governor mandates are estimated to never reopen. There has been an increase in rental and mortgage default payments which will have adverse consequences to the real estate market and increase negative economic affordability issues. The nature of work is changing from going to a headquarters building to working from home which will reshape the prices of inner city commercial properties with subsequent negative spillover effects to local businesses that cater to those workers. The long-term economic consequences from this recession will have long-lasting effects on the pharma industry, just as what happened with the Great Recession.

What does this substantial economic shock mean for the US pharma industry? Researchers have studied various effects of the Great Recession on the healthcare system and pharma industry. The effects from the Great Recession on pharma sales and drug spending are well-researched (see the referenced *Axtria Research Hub* white paper, which documents numerous studies and outlines a research methodology on how to measure recession-induced pharma effects).[3] The Great Recession revealed that the pharma industry is not recession-proof as many people once thought. This research article, however, takes a different look at the effects of a severe recession on the pharma industry.

1.2 White Paper Objectives

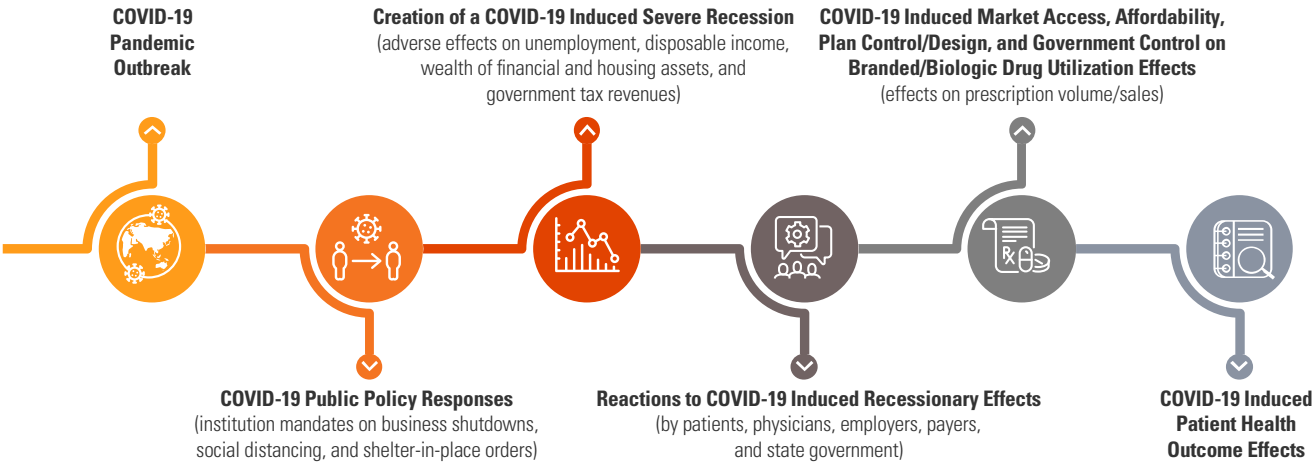
This white paper will explore the relationship between a severe recession, its impact on the pharma industry and drug utilization, and in turn, on patient health outcomes. Researchers have accumulated a significant amount of evidence on the relationship between the US Great Recession and patient health. Prior empirical evidence showed, for example, that overall population health declined in Detroit, which was severely affected by the Great Recession.[4] An excellent survey and easy read of convincing evidence is provided by Amy Gutmann in a Spring 2014 article published in *Harvard Public Health*.[5] This research article therefore highlights a specific relationship related to the topic by connecting a severe recession to health outcomes which has been understudied and is important to pharma companies and the patients they serve – *the decline in health outcomes caused by a decrease in the quantity and quality of pharmaceutical utilization due to the economic effects from a deep and long recession.*

1.3 Four Effects Caused by a Deep Recession

Figure 1 lays out the chain of relationships between the COVID-19 outbreak, its effect of creating a severe recession through public policy lockdown mandates, adverse consequences to drug utilization, and, ultimately, reductions in patient health outcomes. There are four effects caused by a deep recession that will affect adversely the utilization of branded/biologic drugs, which, in turn, will cause a decrease in patient health outcomes:

1) Market access.
2) Plan control/design.
3) Affordability.
4) Government control (state Medicaid).

Figure 1. Basic Pathway of How a COVID-19 Induced Deep Recession Affects a Pharmaceutical-Related Reduction in Patient Health Outcomes



Source: Axtria Inc.

1.4 Company Reactions to a Deep Recession

Understanding these effects and what drug companies can do in response is critical to maintaining their business operations successfully while also serving the needs of patients. Pharmaceutical companies have also been increasingly moving towards performance-based contracts with pharmacy benefit managers (PBMs) as a risk-mitigation and demonstration-of-value strategy approach. Pharma companies will need to be prepared to counter the influence of recessionary effects on health outcomes if these performance-based contracts are to be maintained with PBMs. Lastly, companies have begun to include patient-centric approaches in their commercial model designs. Thus, understanding how a deep recession affects patient health through declines in the quantity and quality of pharmaceutical utilization would be consistent

with companies concerned about the well-being of patients and ways to mitigate those effects through sales, marketing, managed markets, and patient-engagement tactics. This paper will also address five actions pharma companies need to take in response to these adverse effects on patient health:

1) Understand managed market effects.
2) Predict in real-time future local economic conditions.
3) Provide information and assistance that will improve long-term patient adherence.
4) Create a robust analytical capability to produce actionable business insights in real-time.
5) Develop an efficient data management structure to support analytical capabilities.

2. Recession and Drug Utilization Effects

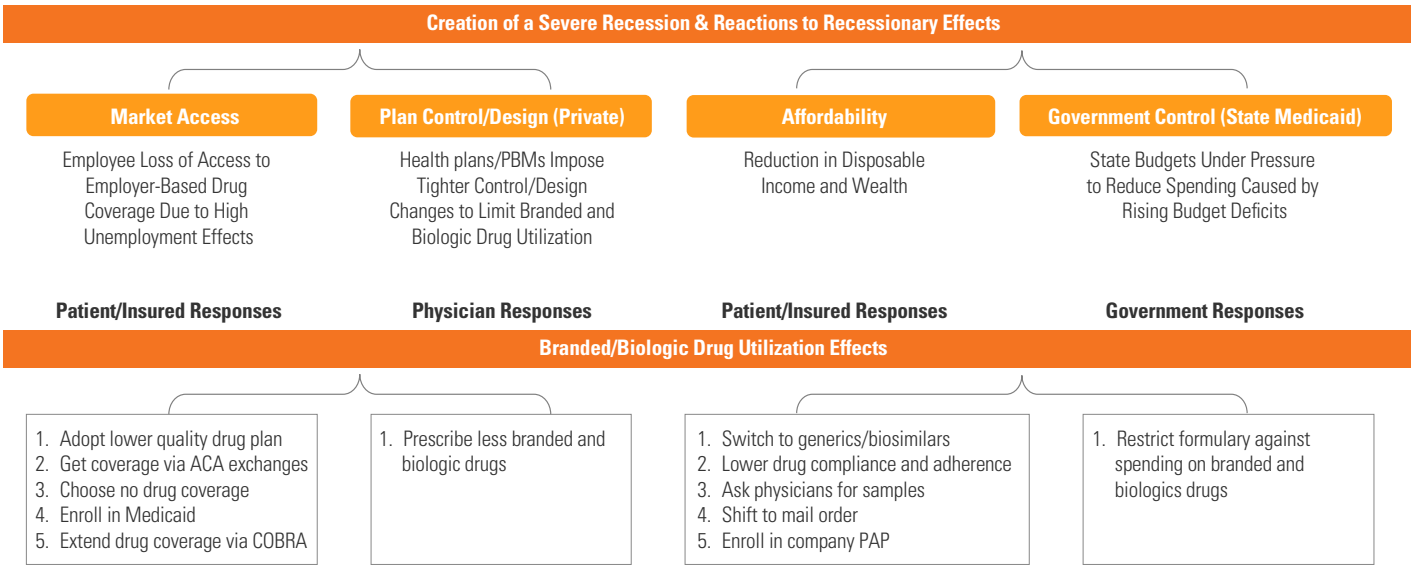
2.1 Insights into the General Pathway of Analysis and Effects

Figure 1 reveals important insights about the pathway of analysis and effects:

1) The recessionary cycle is virus-based, not economic-based. The status of the COVID-19 outbreak will determine public policy responses. COVID-19 will likely be a longer-term event until effective treatments, such as the availability of widespread testing and/or a vaccine, are found. The status of COVID-19 and society's ability to control the outbreak will, in turn, determine public policy responses.
2) The public policy responses are creating severe recession effects, not COVID-19. Fears are being raised about the longer-term consequences to economic growth.[6] The massive accumulation of budget deficits from spending on stimulus programs will stifle the recovery needed to bring society back to economic levels pre-COVID-19.[6] The non-partisan Congressional Budget Office (CBO) projects a $3.7 trillion budget deficit for fiscal year 2020.[7] This means long-term structural issues of higher unemployment and lower disposable income growth that will make persistent market access and affordability problems for medicines by patients.
3) The longer-term existence of COVID-19 and the economic consequences will also affect the response by physicians (in office-based and hospital settings), healthcare systems, payers, and the government that will affect drug utilization, which, in turn, impacts patient health outcomes.

2.2 Four Pathways of Recessionary Effects that Impact Drug Utilization

Figure 2. Market Access, Plan Control/Design, Affordability, and Government Control Reactions to Recessionary Effects on Drug Utilization



Source: Axtria Inc.

Figure 2 illustrates four reactions to recessionary effects on drug utilization:

1) **Market Access.** Employee loss of access to employer-based drug coverage due to high unemployment effects. A deep and long recession means either the loss of health/drug insurance (over half of all non-elderly insured individuals covered under health insurance plans are provided through employers)[8] or movement into lower quality drug plans (e.g., coverage through the Affordable Care Act (ACA) exchanges or Medicaid), producing negative branded/biologic drug utilization *market access effects*. The very high unemployment we are currently experiencing translates into millions of people losing access to drug coverage, thereby increasing out-of-pocket (OOP) costs via cash payment versus generally lower co-pays through insurance, thereby lowering drug utilization. Evidence from the Great Recession revealed that unemployed people could not afford to maintain their health insurance through the Consolidated Omnibus Budget Reconciliation Act (COBRA), which requires people to pay the full premium cost plus an administration fee. Even the 35% subsidy from the Obama administration to reduce the out-of-pocket premium costs was insufficient for unemployed people to maintain health insurance coverage. *The net effect on branded/biologic drug utilization is expected to be negative.*

2) **Plan Control/Design (Private).** Health plans/PBMs impose tighter control/design changes to limit branded and biologic drug utilization. PBMs may exert greater plan control/design mechanisms (e.g., physician-directed: prior authorization, step therapy conditions, and quantity limits; insured-directed: formulary status and tier level). Physician-direct mechanisms are designed to limit physician prescribing of more expensive branded/biologic drugs relative to available generic drugs/biosimilars. Insured-directed mechanisms are designed to make drugs more expensive for covered individuals, thereby reducing utilization. Taking all of these mechanisms into account, the *net effect on branded/biologic drug utilization is expected to be negative.*

3) **Affordability.** Reduction in disposable income and wealth. Unemployment changes are important to assess market access effects for people covered by commercial third party plans, but not individuals who are retired and likely under Medicare. Different economic measures are needed to gauge the severity of a recession. A deep recession also brings about a reduction of disposable income associated with job losses and declines in wealth through financial/real estate downturn market effects. Disposable income and wealth effects are important economic measures across all age groups, but especially for senior citizens who are retired and live on a fixed income. The elderly use saved financial assets and built-up equity in their homes as vehicles to fund their retirement. The Great Recession was damaging because it adversely affected employment, disposable income, and wealth. Patient socio-demographic characteristics of a drug will determine which economic measure(s) are more salient and adversely affect drug utilization. Evidence from the Great Recession revealed significant brand-to-generic switching, lower adherence and compliance (e.g., people stopping their medications or taking their once/day drug once every other day), higher demand for samples, greater use of mail to reduce prescription costs, and higher enrollments in company patient assistance programs (PAPs). *The net effect on branded/biologic drug utilization is expected to be negative.*

4) **Government Control (State Medicaid).** State budgets under pressure to reduce spending caused by rising budget deficits. A deep recession will depress state government revenues, influencing public policy efforts to exert greater controls to limit the reimbursement of branded/biologic drugs under Medicaid. *The net effect on branded/biologic drug utilization is expected to be negative.*

2.3 Summary of Key Points of Recessionary Effects on Drug Utilization

A summary of key points from **Figure 2** reveals the following insights on the relationship between a severe recession and drug utilization:

1) Recessionary effects will impact branded/biologic drug utilization through different economic variables. Viewing recessionary effects through the narrow lens of unemployment alone is not sufficient.

2) All four pathways show adverse net effects on branded/biologic drug utilization through a recession via various mechanisms.

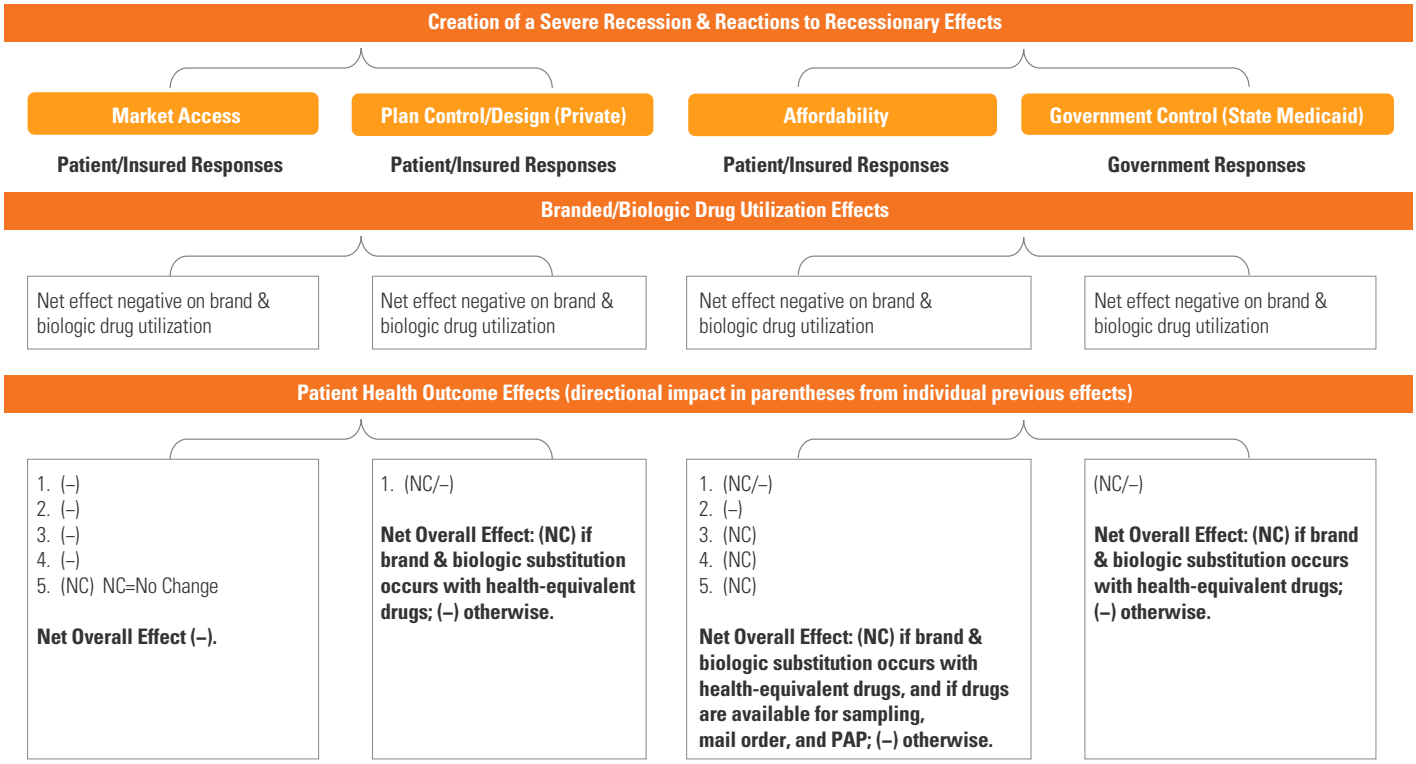
3) *Market Access* (given the very high rate of unemployment) and *Affordability* (reductions in disposable income due to unemployment and mandated business shutdowns, and wealth effects due to financial market losses) effects will likely be the strongest factors driving adverse declines in branded/biologic drug utilization. Pharma company commercial policies should be directed in these areas to mitigate, resulting negative effects on drug utilization and potential adverse consequences to patient health outcomes (see the next section for further details and an explanation on these effects).

4) The pathways of adverse effects on drug utilization outlined in **Figure 2** can be easily modeled, estimated, and measured at the brand metropolitan statistical area (MSA) using econometric methods. Resulting "drag" effects from the recession (i.e., recession effects pulling down prescriptions relative to their potential level for the situation when the recession does not exist). This means pharma companies can weigh the effects from recession variables relative to management control variables on brand demand, and understand how changes in sales, marketing, and managed market variables can be changed at the brand-MSA level to reduce negative drug utilization effects. See **Appendix Figures A1, A2,** and **A3** for an explanation of how this modeling work could be done.

3. Drug Utilization and Pharmaceutical-Related Patient Health Outcome Effects

3.1 Overview of Patient Health Outcome Effects

Figure 3. Market Access, Plan Control/Design, Affordability, and Government Control Reactions to Recessionary Effects on Overall Drug Utilization and Patient Health Outcomes



Source: Axtria Inc.

Figure 3 expands on the preceding outlined effects on drug utilization by providing more detailed pathways and shows how a severe recession affects a change in pharmaceutical-related patient health outcomes.

3.2 Detailed Pathway Analysis of Patient Health Outcome Effects

The detailed pathway analysis outlined in **Figure 3** on pharmaceutical-related patient health outcome effects provides the following insights:

1) *Market access* impacts will generate the greatest negative effects on patient health outcomes. Extending *market access* for drug utilization through COBRA assumes people can afford continuing coverage at a much higher cost. *Affordability* will likely come into play, thereby dominating this specific *market access* effect and thus reducing utilization.

2) There are a number of circumstances where "NC" (No Change) is expected on patient health outcomes, though based on some qualifying assumptions happening. If these qualifying assumptions do not happen, then these "NC" effects can easily become "negative":

a) If bioequivalent generic drugs do not exist for a patented branded drug, then patient health outcomes can decrease if patients are provided with a therapeutic generic substitution (different molecule) that produces a lower quality health outcome.

b) The preceding argument is also applicable if either a reference biologic substitution to a biosimilar drug does not exist, and even if one does exist, is the biosimilar "interchangeable" with the reference biologic drug? The lack of biosimilar substitution and/or one that is not "interchangeable" to the reference biologic will mean that potentially these pathways will produce "negative" patient health outcomes.

c) If generic and/or biosimilar drugs are not available to counter *affordability* issues via sampling, mail order, or on a company PAP, then overall effects on patient health outcomes will turn negative.

3) The overall consequence of the preceding discussion and relationships outlined in **Figures 2 and 3** means that the relationship between a severe recession producing negative patient health outcome effects is a very distinct possibility.

4) The empirical analysis to determine patient health outcome effects can also be modeled, estimated, and measured. The most straightforward approaches could be the following:

a) Use propensity modeling (commonly applied to healthcare observational data where no control group exists) to connect empirical changes in the level of drug utilization due to a recession with patient health outcomes by applying claims data and electronic health records.

b) Model drug adherence as the dependent variable against a vector of the right-hand side (RHS) variables, including recessionary effects. Then use clinical trial data to determine the relationship between changes in drug adherence with the likelihood a patient receiving indicated drug benefits to measure health outcome effects. This approach is a two-step analytical procedure.

5) While the focus here is on the effect of a severe recession on patient health outcomes, it is very possible that a further "outcome effect" can occur on treatment costs. New and more effective drug technology often results in lower overall treatment costs.[9] Health economic and outcomes research (HEOR) and real-world evidence (RWE) modeling can be instituted to determine treatment cost effects as a result of a severe recession.

4. Pharma Company Actions to Mitigate Patient Health Outcome Effects

The following five company actions can be taken to mitigate adverse pharmaceutical-related patient health outcome effects caused by a COVID-19 induced recession.

4.1 Understand Managed Market Effects

Understand managed market effects, through changes in *market access*, plan *control/design*, and *government control/Medicaid* mechanisms.

a) Analyze how contracting efforts will be critical in reducing co-pay (*affordability*) issues (thus improving adherence) for patients and restrictions placed on physicians to prescribe branded/biologic drugs.

b) Generate analytical modeling to determine how *plan control/design* changes will affect physician prescribing away from branded/biologic drugs that can produce lower patient health outcome effects. Understand and measure recessionary effects on branded-to-generic drug/reference biologic-to-biosimilar substitution and on health outcomes.

c) Apply HEOR and RWE modeling to leverage patient-level claims and electronic health records to elicit adverse health outcome effects through changes in plan design/controls.

d) Develop HEOR and RWE model designs and empirical analyses to demonstrate the value of new specialty medicines, especially in oncology, as the industry will see an acceleration of the use of health technology assessments (HTAs), as employed by The Institute for Clinical and Economic Review (ICER), to challenge drug pricing.[10]

e) Use coupons, co-pay cards, and vouchers to mitigate *affordability* issues brought about by severe local economic conditions. Empirical analyses must be applied to determine their economic rationale on the basis of maintaining drug utilization and producing health outcome benefits through keeping patients adherent.

4.2 Apply Artificial Intelligence and Machine Learning

Apply artificial intelligence (AI) and machine learning (ML) to predict in real-time future local economic conditions. Severe economic conditions in urban geographic areas are likely to see greater adverse economic effects on patient health outcomes per the preceding mechanisms affecting drug utilization.

4.3 Develop Sales, Marketing, and Patient-Oriented Approaches

Develop sales, marketing, and patient-oriented approaches to ensure physicians and patients receive necessary drug information and assistance that will improve long-term patient adherence.

a) Employ an omnichannel, as opposed to a multichannel approach to customer engagement.

b) Ensure the sales force disseminates valuable scientific, clinical, and medical information to HCPs needed to improve the treatment of their patients. This means leveraging medical science liaisons (MSLs) and key opinion leaders (KOLs) to demonstrate drug value and benefits relative to risk.

c) Create the capability for sales reps to offer indirect engagements with HCPs via the use of digital technologies, while ensuring those connections are measured and analyzed for drug utilization and health outcome effectiveness.

d) Use non-personal promotion channels, such as direct-to-consumer advertising (DTCA), via all mediums and search engine capabilities to help with information search to inform patients/caregivers about the value of taking their medicines and availability of programs to help with lowering OOP costs. Direct-to-patient advertising (DTPA) done in physician offices should be employed, but once people are feeling more comfortable seeing their doctor.

e) Make it easier for patients to receive 90-day prescriptions as a way to maintain/improve drug adherence. This means, where possible, to make drugs available via mail order.

f) Promote to patients the benefits of enrolling in a disease management program to give them needed information to manage effectively their disease and the importance of proper compliance and adherence necessary to receive full indicated drug benefits.

g) Allow samples to be allocated as a way for physicians to encourage trial usage for patients who are not achieving desired clinical endpoints. However, caution should be exercised in allowing sales reps to use samples for simply gaining HCP access (sales training can minimize this behavior) and engaging in over-sampling resulting in cannibalization of prescriptions.

4.4 Create a Robust Analytical Capability

Create a robust analytical capability to produce actionable business insights on the preceding research questions and topics. Proper analysis of these questions/topics requires crossing traditional siloed pharmaceutical functions. The use of analytics can bring about needed interdisciplinary insights and solutions into these problems, and help with cross-functional alignment when it comes to execution.

4.5 Develop an Efficient Data Management Structure

Develop an efficient data management structure and ability to link databases to enable cross-function analyses on the preceding research questions and topics. Databases used in the analysis of health outcomes are fundamentally different than those employed in traditional pharma commercial analytics. Effective linking of these databases will be required to create a more complete picture and to determine how traditional commercial channels can affect patient health outcomes.

5. Concluding Remarks

This white paper extends previous research work on the impacts of a severe recession on drug utilization to determine the pathways of producing adverse effects on pharmaceutical-related patient health outcomes. All economic signals point to a severe and longer COVID-19 induced recession far greater than the Great Recession, especially given the likelihood of the virus reappearing during the next flu season, existing limitations on widespread testing, and the country having no available vaccine until at least 2021. Federal Reserve Chairman Jerome Powell has publicly warned about the prospect for a prolonged recession after the coronavirus.[11]

The Great Recession had a transformative effect on the pharmaceutical industry. The "Great Lockdown" is almost certain to have similar transformative and long-term effects on the industry. This white paper provides pharmaceutical executives with detailed insights into how a severe recession will affect not only drug utilization and patient health outcomes, but also a framework to analyze what companies can do to mitigate those adverse effects.

Appendix

The following three figures provide more details and insights respectively on how and the value of developing brand utilization, financial drag, and patient health outcome effects from a COVID-19 induced recession analysis.

Figure A1. Inferential Brand-Urban Level Model Development & Estimation Requiring Advanced Econometric Methods

Development of Inferential Model for Prediction & Scenario Analyses

Start with a traditional multi-channel promotion/payer-response panel data model specification with added economic variables to account for urban area recession effects

$NRx_{gt} = f(\alpha_{gt}, \beta \mathbf{SM}_{gt}, \delta \mathbf{P}_{gt}, \theta \mathbf{E}_{gt}, \lambda \mathbf{X}_{gt}, \varepsilon_{gt})$; Model design in vector form for RHS variables

NRx	= Brand new prescriptions
SM	= Vector of sales and marketing variables
P	= Vector of payer/market access related variables
E	= Vector of economic variables
X	= Vector of exogenous variables (e.g., COVID-19 related metrics)
α	= Constant; ε = Error term
β, δ, θ, λ	= Vectors for RHS variable parameters
t	= Time period (month); g = Geographic area

- Initial estimation of pooled cross-sectional and time-series defined variables assumes a fixed-effects model approach.
- Alternative is a random coefficients model approach by allowing parameter estimates to vary by MSA geography unit g.

Comments: The general framework outlined in this figure can be modified to look at drug adherence (as a leading indicator of health outcomes) or patient health outcomes as the dependent variable. The use of propensity modeling to look at resulting effects from each explanatory variable can then be undertaken to measure recession effects. An analysis of drug adherence will require another structural model to connect changes in the dependent variable with patient health outcomes. Finally, adjustments in this general framework can be done to look at effects on total treatment costs and cost-effectiveness.

Source: Axtaaria Inc.

Figure A2. Inferential Model Used for Prediction and Scenario Analyses to Determine Company Recession Response

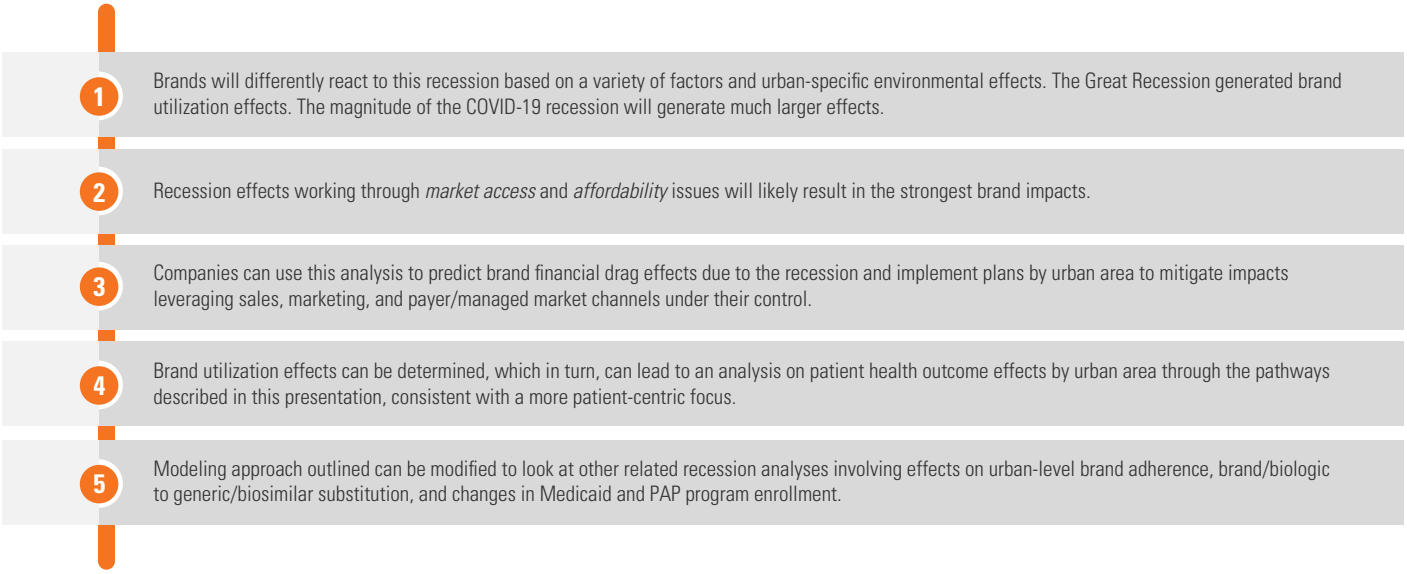
Prediction & Scenario Analyses Used for Budget Reallocations

- Recession effects by urban area different given variations in the severity of the COVID-19 and policy responses in response to the outbreak.
- Urban-level analysis with geographic-specific parameter estimates will allow for targeted channel responses that are most appropriate for that area.
- Pharma company can measure the predicted brand financial drag effect mitigated relative to the spending required to achieve that result by scenario, thereby allowing for a ROI calculation to determine the Next Best Action.
- Analyses will also show brands being affected differently from the recession requiring different budget reallocations of sales, marketing, and managed markets variables.

Comments: The general framework can be used for scenario analyses, applying the following approaches: 1) inserting predicted future economic variables and then computing the effect on the dependent variable based on planned company-controlled measures, or 2) transforming the model by using principle components analysis (PCA) and then calculate predictions of each scenario run.

Source: Axtria Inc.

Figure A3. Valuable Insights to be Gained from a COVID-19 Induced Recession Analysis



Source: Axtria Inc.

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