Proposing Securitization of Outcomes-Based Agreements in BioPharma as a Hedge for Longevity Risk

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Authors:
Jennifer Hinkel, MSc, BS
Arka Ray, BS
Sirtaj Singh Brar, BS

Corresponding Author:
Sirtaj Singh Brar, BS
The Data Economics Company
sirtaj@lydion.com

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Introduction: A Proposed Novel Hedge for Longevity Risk

Institutional investors in the 21st century have numerous incentives for seeking opportunities to hedge against longevity risk, particularly as obligations to Baby Boomer-era retirees mount at the same time that life expectancy in the US has trended longer (at least until the downstream consequences of the COVID-19 pandemic are fully realized in morbidity and mortality data). Longevity Risk specifically refers to the risk of increasing life expectancy and longer, or larger, payouts funded by entities holding financial risk for pension and retirement funds and similar insurance or annuity instruments.

Retirement and pension plans with defined payment benefits (such as a percentage of pre-retirement salary due as long as the retiree is alive) feel this risk most intensely. With the retirement of the Baby Boomer generation (many of whom do not have significant assets or savings beyond home ownership) coupled with record-low interest rates since the 2008 global financial crisis, pension plans and funds are at risk of not being able to meet required payments to their beneficiaries, particularly as these beneficiaries live longer due to innovative health interventions.

As an example of relatively rapid shifts in life expectancy and mortality risk for high-incidence diseases among the elderly, survival rates for lung cancer, one of the most common cancers, have been improving at accelerating rates over the past two decades. Lung cancer mortality in men declined 3.2% per year from 2006-2013 and then 6.3% per year from 2013 to 2016. (Howlader et al. 2020) These improvements in survival occurred prior to the approval in lung cancer of anti-PD1 and anti-PDL1 agents as well as several other "targeted therapies" that provide "personalized" treatment options based on molecular-level alterations or mutations in tumor DNA or RNA. Some patients treated with these newer agents have long-lasting, durable remissions that make cancer more of a chronic disease than a pressing crisis. (Eisenstein 2020)

Given the inverse relationship between longevity risk and biopharmaceutical industry breakthroughs in diseases such as cancer, Alzheimer's, and cardiovascular disease, investment in the biopharma and life sciences industry might appear to be one obvious hedge. However, publicly-traded biotech, pharma, and life sciences equities combine a number of risks, as well as a number of drug assets across a company portfolio. A company with a promising Alzheimer's treatment can out-license to another firm and lose potential upside, or a company can decide to divest itself of entire therapeutic areas, as Glaxo-SmithKline did with its oncology (cancer) business in 2015, selling those assets to Novartis before re-entering the cancer market by purchasing Tesaro in 2018.

A more targeted approach to hedging against longevity risk would be an investment not in biotech/pharma equities, but in the performance of key drug products or molecules, particularly when they have the potential to significantly alter the life-expectancy within a particular disease state (as the PD1/PDL1 products have done in a subset of lung cancer patients). While a

financial instrument to invest in this manner does not currently exist in the market, we propose that a mechanism to create one might exist given the adoption among both biopharma manufacturers and health payers (insurers) of "Outcomes Based Agreements" (OBAs). OBAs are essentially drug pricing contracts that modulate payment level from the insurer to the manufacturer depending on the real-world results of the biopharmaceutical product. OBAs can specifically capture risk of the drug product's performance, and if translated into a financial instrument investable by third parties, unexpected over-performance of a drug that led to longer life expectancy could also yield financial upside.

Longevity Risk Mitigation

Financial products and methodologies do exist in the current market allowing pension funds to offload some level of longevity risk, including those structured around bulk annuities from life insurers and mortality-linked contracts that are not correlated with market risk.

The methods for hedging longevity risk can be roughly split into two types of contracts. (Li and Hardy 2011) The first type is created by estimating the mortality of each member of a specific pension scheme, then entering into a swap agreement with a counterparty in which the counterparty will assume responsibility for making payments to the plan's members, including any members whose lifespans exceed the expected mortality rate. In exchange, the pension plan will make fixed payments to the counterparty regardless of the realized mortality rates of the plan's members. This swap mechanism allows the pension to eliminate uncertainty about its future liabilities by transferring all potential variability to the counterparty. The counterparty (often a life insurer) also has potentially significant benefit from this trade depending on the degree to which their liabilities mirror those of the pension plan. While highly effective at eliminating longevity risk, contracts of this type require the collection and analysis of large amounts of data on each member of the pension, resulting in both high implementation costs and a lack of liquidity.

An alternative to the swap mechanism is the less-customized q-forward derivative contract introduced by J.P. Morgan in 2007. Instead of tailoring the swap to precisely hedge the liabilities of one pension scheme, a q-forward is pegged to the nationwide expected mortality rate of a given country. The structure of a q-forward is not markedly different from any other longevity risk swap, in which one party agrees to pay a fixed rate while another party pays a variable rate and the payouts are reconciled at maturity, except in this case the fixed rate is chosen based on mortality data for a national population. This standardization makes the q-forward a significantly cheaper and more liquid option for offsetting longevity risk. However, it fails to account for the likelihood that the realized mortality rate of a pension scheme will almost inevitably deviate from the realized mortality rate of the corresponding national population to which the q-forward is linked. This leftover risk is referred to as population basis risk.

These two methodologies illuminate a clear trade-off in the market for longevity risk hedges between the price of a contract and the robustness of the hedge. Highly customized longevity swaps are generally more comprehensive and expensive, whereas capital markets solutions such as q-forwards reduce price at the cost of not completely covering the risk.

As the market for longevity-linked securities continues to grow in order to address these risks, so too will demand for more unique and innovative hedging tools. Hedging instruments linked to the real-world performance of life-saving or life-extending health care interventions including drugs and biologics are one such innovative tool that we propose.

Outcomes Based Agreements and Outcomes Based Agreement Derivatives

Outcomes-Based Agreements (sometimes referred to in the health care sector as Value-Based Agreements, Risk-Sharing Agreements, or Managed Market Entry Agreements) are dynamic pricing contracts entered into between biopharmaceutical manufacturers and health care insurers, or occasionally between health care provider systems and health care insurers.[1] Such agreements can be structured in numerous ways, but at the core involve a fluctuating price (or discount) for the health product or service based on an outcome, clinical or otherwise, for individuals or for a population. In one instance, a manufacturer may offer a deeper discount to a payer if, across the population of the payer's beneficiaries who are treated with the drug, a certain target (such as a cholesterol reduction of x%, or a reduction in emergency room visits by y%) is not met. Another structure sees a discount applied if a patient does not respond to treatment. A third may see a variable discount based on how much money is saved by the payer, for example, in the case of a drug which costs more than competitors on a per-pill basis, but has a much better safety profile so that beneficiaries are not at risk for safety-related adverse events and related expensive hospitalizations.

While OBAs are relatively nascent in pharmaceutical and payer markets, a number of documented hurdles to their adoption and implementation, such as the advent of new technology and data tools, removal of regulatory barriers, and market pressure to innovate in drug pricing are expected to accelerate adoption in both US and European markets. From a risk perspective, however, neither biopharmaceutical companies nor health insurers are traditionally equipped to handle the uncertainty and risk associated with performance-based payments. Therefore, the availability of outside capital provided by parties who may have appetite for such risks could serve to significantly accelerate OBA adoption. Additionally, if multiple OBAs were to exist across different drug products, disease areas, and beneficiary populations, bundling and securitizing various OBA-associated risks into financial derivative products may prove attractive to a number of investor types, including those who typically invest in biotech/pharma equities.

[1] For more in-depth reading on the market for OBAs, adoption trends, and barriers to implementation, see XYZ (link on Insider?)

OBAs and Longevity Risk Hedging

In designing an effective longevity hedge (and hedges in general), the hedger typically seeks to purchase assets whose returns have minimal correlation to traditional market risk factors. For this reason, private equity, infrastructure, and real estate are all popular investments for pension funds, as these asset classes can more reliably weather market volatility than stocks and bonds.

Despite its goal of developing products to improve health and lifespan, the biopharmaceutical industry remains largely uninvestable for those seeking steady, reliable returns. Publicly traded life sciences equities, whether "big pharma" or emerging biotech, have historically proved to be unreliable investments as their shares are often volatile and frequently subject to rampant speculation, not to mention potential shocks from regulatory and policy actions. As a result, such equities are less viable additions to the portfolios of risk-adverse institutional investors. As a frame of comparison, predicting whether a drug is likely to receive FDA approval within a specific timeframe (and as a result, potentially make or break a company's share price) is much more difficult than estimating consumer demand for Ford trucks.

However, as the health care sector as a whole pursues a transition to more "value-based", "performance-based", and "outcomes-based" pricing and payments, in which financials become more aligned with real-world results of the products they manufacture, an investment opportunity may exist for those who seek to capitalize on this shift while mitigating risks that would typically accompany biopharma shares.

This landscape represents a significant opportunity for the capital markets. By inviting investment from outside parties with higher tolerance for risk, manufacturers and payers can reap the benefits of OBAs (including, potentially, expanded market access or reduced spending on less-effective treatments) without having to assume untenable financial liabilities (or, more generally, liabilities outside of their usual business models). For investors seeking to make highly targeted bets on pharmaceuticals and related products, individual OBAs could give investors unique exposure to the outcomes of specific treatments—even potentially within specific patient populations.

Alternatively, if one were to bundle and securitize a number of OBAs corresponding to treatments in one therapy area, an investor could place more broad bets on the landscape for those treatment types as a whole. In this way, the terms of OBAs are no longer constrained by only two parties and can begin to reflect the risk appetites of the larger investment community, resulting in potentially steeper discounts on treatments and higher rewards for desired outcomes when achieved. Most importantly, the value of an OBA is unaffected by much of the noise that generally impacts biopharma shares. Where stock prices are influenced by myriad factors (including Wall Street's faith in management, macroeconomic factors, and policy decisions), an OBA's price better reflects the performance of the underlying product in reaching a predefined clinical or non-clinical outcome. This feature could make OBA instruments less

appealing as mainstream investment vehicles. However, the same feature could result in a unique value proposition for a specific set of investors.

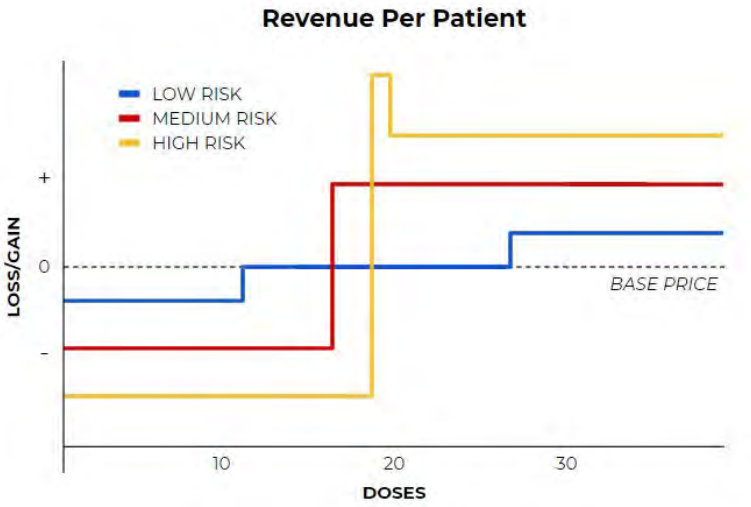
An example scenario in cancer therapeutics

Below is a hypothetical example of a pharmaceutical manufacturer bringing a cancer immunotherapy product in the PD1/PDL1 inhibitor class to market for lung cancer patients. In this scenario, we assume that the manufacturer has entered into an OBA with a major health insurer to maximize market access. Perhaps the insurer prioritizes this product above class competitors in its formulary, meaning patients might have a lower co-pay, or prescribers aren't required to jump through paperwork hoops for reimbursement approval.

The structure of our hypothetical agreement is duration-based; the longer a patient remains on the treatment, the more likely the patient is improving (or the disease is not worsening), resulting in a higher payout to the manufacturer, while patients who are switched away from this treatment, whether due to lack of benefit or intolerable side effects, yield little to no payment for the manufacturer. According to the OBA, cash flows are scheduled in such that the first set of doses to each patient are discounted the most heavily from list price, after which the discount is gradually reduced to the point of being eliminated as the patient remains on treatment.

Depending on the exact terms of the OBA, later doses might even come at a premium to base price as a reward for the success of the treatment in achieving a long-term remission (or lack of progression/"progression free survival" or PFS). In the case of the most aggressive discounting schedule, once the patient has remained on the treatment for an agreed-upon number of doses, the manufacturer could receive a bonus (reimbursement for the higher initial discounts) as well as a small premium on each subsequent dose. The graph below illustrates the various discount schedules relative to the base price of the treatment on a per patient basis.

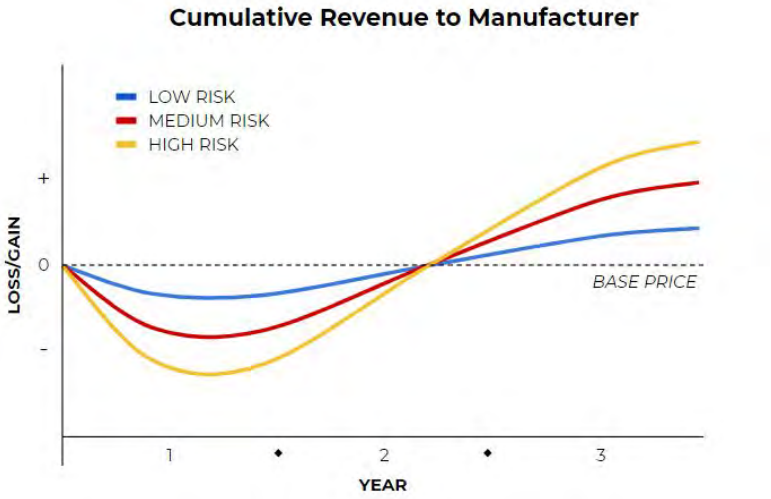
Figure 1: Revenue Per Patient over Dosing Duration



The high, medium, and low discount schedules illustrate how the contract can reflect varying degrees of risk as more/less aggressive discounting results in higher/lower potential returns. Discounts can be a function of time (the number of doses for which the discount is given) as well as price (the deviation from base price), although in this example more-aggressive discounts are both given for longer periods and at steeper rates.

The following graph depicts the cumulative returns to the manufacturer that they might expect over the three-year lifespan of the contract relative to what they may have forecast had the product been sold at base price. In this example, the treatment is demonstrated to outperform, meaning that the average patient remained on the treatment long enough to result in the manufacturer receiving higher compensation over the full time period than they would have received without the OBA in place.

Figure 2: Revenue to Manufacturer over OBA Time Period



The shape of the curve in the first year is indicative of the reduced revenue that the manufacturer will face as it provides discounts to all incoming patients before any of them have received enough doses to merit a bonus payout. Over the course of the second year, losses are reduced as sufficient durations of treatment are observed in the patient cohort, resulting in the generation of bonuses that offset the discounts.

Finally, in the third year, the manufacturer sees their bet start to pay off as enough patients from the initial cohort remain on the treatment long enough to generate upside on the contract. From the graph, we can observe the potential for multiple parties to make investments of varying risk/return profiles that correspond to their appetites for risk as well as the types of liabilities they are seeking to offset.

We forecast that many OBAs will convey a similar structure to the prior example, in which the manufacturer accepts initial losses, or risk of losses, in exchange for potentially higher payouts whether in the form of increased unit reimbursement or wider access (higher volume) to beneficiaries as agreed-upon outcomes, clinical or otherwise, are met.

Considering another example, a manufacturer of an Alzheimer's treatment agrees to provide the treatment for free until it can be observed that the patient's condition is not progressing, after which the insurer will agree to cover any further treatments for the next two years. (Carlson et al. 2010) Given the scope of the financial impact that a treatment, let alone cure, for Alzheimer's would have on most pension funds, enormous incentives exist for pension funds to make investments that would allow their participation in the financial upside of such a treatment.

The Path Ahead

The rise of OBAs, particularly those based on clinical outcomes that correlate with life expectancy, represent a compelling opportunity for pensions and life insurers seeking new ways to cover their liabilities. When the upside of the contract corresponds to how well a drug actually works in real-world populations to improve life and health, it isolates a fundamentally causative element of improved longevity: tangible improvements in health care and health outcomes. The timing could hardly be better; as institutional investors face mounting pressure to allocate funds towards companies and assets that are demonstrably beneficial to society, there is an opportunity for Wall Street to lean into the societal benefits of creating and investing in financial products correlated with improving people's health. Moreover, such financial products may also prove of interest to traditional biotech and pharma equity investors, as they provide an opportunity to capture different, and at times more specific, risks, and may hedge against health policy shocks such as government intervention in drug pricing that adversely impact biopharma equities, particularly as OBAs are seen as a "better deal" for government and private insurers and are viewed favorably by US and European governments.

In terms of a market for such financial products, by finding a mechanism to transfer some of the OBA performance risk away from biopharma manufacturers and insurers to more suitable parties, the expectation is that those same manufacturers and insurers will be more incentivized to engage in OBAs, as neither party will be exposed to all potential downsides in the contract. We see this having a procyclical effect on the OBA market, as demand for effective hedges should spur the implementation of more contracts that potentially improve or accelerate patient access to new therapeutics , potentially leading to an overall healthier population and further demand for OBAs. With enough OBAs on the market, the possibility arises for securitization and indexing, allowing investors to purchase, for example, upside in life improvements from new cancer treatments, or even improvements for specific disease subtypes or disease subpopulations, including those with more rare diagnoses. Our recent research efforts have focused on building pricing models that can illuminate how one could invest in a single OBA, as well as exploring mechanisms for bundling such assets.

So, why should institutional investors—specifically pension funds and life insurers—care about OBAs? Simply put, pensions, life insurers, drug manufacturers, and health insurers all have the potential to reduce their liabilities while fostering the next generation of investment instruments in the healthcare industry.

Technological Facilitation of Data-Backed Agreements and Financial Instruments: Applicability of the Lydion DEOS

The authors are part of The Data Economics Company (DECO), a science and technology company that is developing the Lydion Data Economics Operating System (DEOS) platform, and that has a specific interest in how technology platforms such as the Lydion DEOS can facilitate OBAs and OBA Derivative instruments. The Lydion DEOS and related applications have already been demonstrated in the OBA market, and examples have been presented to financial, technology, and health care audiences. (Dean, et al. 2018; Hinkel et al. 2019a; Hinkel et al. 2019b)

Even with a fit-for-purpose software platform in place, fundamental financial constraints may hinder the rapid growth of the OBA market, and, despite a push from payers, OBAs have not yet expanded their reach to the point of sharing the risk outside of the health care industry supply chain.(Carlson et al. 2010)

In addressing the challenges posed by Outcomes-Based Agreements, we see data economics as an indispensable tool not only for creating and implementing OBAs, but also for the ongoing management and assessment of how such contracts are performing in the field. The Lydion DEOS enables market participants to dynamically account for and track all relevant data for each contract, leading to better pricing and risk management practices and an overall healthier market.

As is the case with any financial instrument, understanding the value of the contract at any point in its lifespan is largely a function of having the necessary data to measure the performance of the underlying factors on which the contract is based. For a more straightforward instrument such as an interest rate swap, the reference rate will usually be readily available, making periodic pricing a relatively simple task. However, when considering the data-intensivity of measuring health outcomes, having the right systems in place to collect and interpret these outcomes is an absolute must-have for being able to accurately price (and thus sell) such contracts. By making the initial investment of creating a software solution for this data adjudication problem, DECO has positioned itself to help develop the growing market for OBAs and continues to devote resources to that end, and with the help of our financial partners we hope to remain at the vanguard of these developments.

Works Referenced and Cited

Barrieu, Pauline, Harry Bensusan, Nicole El Karoui, Caroline Hillairet, Stephane Loisel, Claudia Ravanelli, and Yahia Salhi. n.d. "Understanding, Modeling and Managing Longevity Risk: Key Issues and Main Challenges." Article submitted to Operations Research.

Barrieu, Pauline, and Luitgard A. M. Veraart. 2016. "Pricing Q-Forward Contracts: An Evaluation of Estimation Window and Pricing Method under Different Mortality Models." Scandinavian Actuarial Journal 2016 (2): 146–66.

Carlson, Josh J., Sean D. Sullivan, Louis P. Garrison, Peter J. Neumann, and David L. Veenstra. 2010. "Linking Payment to Health Outcomes: A Taxonomy and Examination of Performance-Based Reimbursement Schemes between Healthcare Payers and Manufacturers." Health Policy 96 (3): 179–90.

Dean, B. W., J. M. Hinkel, and W. McGivney. 2018. "Evaluating A Conceptual Platform for Facilitating and Scaling Pharmaceutical Risk Sharing Arrangements." Value in Health: The Journal of the International Society for Pharmacoeconomics and Outcomes Research 21 (May): S50.

Deng, Yinglu, Patrick L. Brockett, and Richard D. MacMinn. 2012. "Longevity/Mortality Risk Modeling and Securities Pricing." The Journal of Risk and Insurance 79 (3): 697–721.

Eisenstein, Michael. 2020. "New Lung-Cancer Drugs Extend Survival Times." Nature 587 (7834): S10–12.

FPL Capital. 2018. "The New 60/40." Retrieved from https://www.fplcapital.com/wp-content/uploads/2018/05/Stone-Ridge-The-New-60-40.pdf

Hinkel, J.M. and Ray, A. 2018. "A technological approach for the implementation and automation of Value Based Agreements between pharmaceutical manufacturers and payers." Lydion Research whitepaper.

Hinkel, Jennifer M., Arka Ray, Sirtaj Brar, and Rahul Lalmalani. 2019. "Modeling an Oncology Outcomes-Based Contract Using a Blockchain Database Approach: Cost and Technology Considerations." Journal of Clinical Oncology: JCO 37 (15_suppl): e18360–e18360.

Hinkel, J. M., S. S. Brar, R. J. Lalmalani, and A. Ray. 2019. "Proposing And Evaluating A Design For Gdpr-compliant, Scalable Technology For Automatic Adjudication Of Risk-sharing Agreements." Value in Health. https://doi.org/10.1016/j.jval.2019.09.1940.

Howlader, Nadia, Gonçalo Forjaz, Meghan J. Mooradian, Rafael Meza, Chung Yin Kong, Kathleen A. Cronin, Angela B. Mariotto, Douglas R. Lowy, and Eric J. Feuer. 2020. "The Effect of Advances in Lung-Cancer Treatment on Population Mortality." The New England Journal of Medicine 383 (7): 640–49.

Li, Johnny Siu-Hang and Hardy, Mary R. 2011. "Measuring Basis Risk in Longevity Hedges." North American Actuarial Journal 15 (2): 177-200.

Pew Charitable Trusts. 2019. "The State Pension Funding Gap: 2017." Retrieved from https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2019/06/the-state-pension-funding-gap-2017

