# Arriving Now — Rare Disease Therapies $500,000 and Higher: Plan Sponsors Take Warning!

37TH ANNUAL ISCEBS EMPLOYEE BENEFITS Symposium


**Ryan A. Siemers, CEBS**
Principal
Aegis Risk LLC
Alexandria VA


The opinions expressed in this presentation are those of the speaker. The International Society and International Foundation disclaim responsibility for views expressed and statements made by the program speakers.

PARTNERS IN EDUCATIONAL EXCELLENCE

# Three Key Takeaways

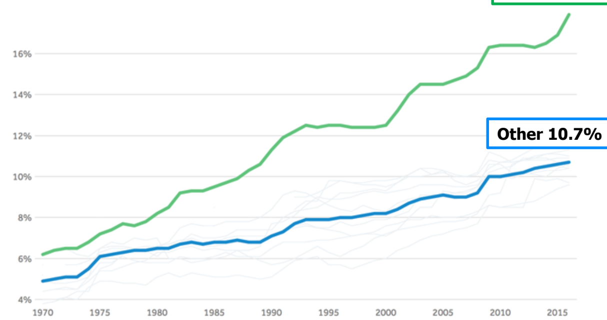
- Awareness of the financial severity of these claimants
  - Beware their size…and potential to remain ongoing
  - Underlying condition is often congenital or hereditary – and rare
  - Revenue objectives of Wall Street and Pharma may foil effective pricing
- Understanding of risk management approaches
  - Ensure forward strategies with health plan and PBMs
  - At what threshold should any plan "build a fence" to protect itself?
  - Stop loss remains the prevalent approach, but how to improve it
- Discussion of potential pitfalls with stop loss and risk transfer
  - Understand this is not an employee benefit; it's a plan sponsor risk
  - Respect the Disclosure process; its requirements; and its objective
  - What may the future hold for such costly reimbursements?

# Health Care Is Big Business..in the U.S.

Total health expenditures as percent of GDP, 1970 - 2016

US 17.9%

Other 10.7%




Excludes spending on structures, equipment, and noncommercial medical research. Data unavailable for: the Netherlands in 1970 and 1971; Australia in 1970; Germany in 1991; and France from 1971 through 1974, 1976 through 1979; 1981 through 1984, and 1986 through 1989. These countries are not included in calculated averages for those years. Break in series in 2003 for Belgium and France and in 2005 for the Netherlands. Data for 2016 are estimated values. The 2016 US value was obtained from National Health Expenditure data.

Source: Kaiser Family Foundation analysis of data from OECD (2017), "OECD Health Data: Health expenditure and financing: Health expenditure indicators", OECD Health Statistics (database) (Accessed on March 19, 2017). • Get the data • PNG

Peterson-Kaiser
Health System Tracker

- In 2017, Health Care is nearly 18% of the US GDP
- Notably exceeds comparative, developed economies
- Largest job source in the US
- Employer-funded health care means **your plan pays for it!**

# High Dollar Claims – A Timeline

**2010**
- ACA removed annual & lifetime dollar limits
- 59% of health plans had lifetime limits in 2009 (Kaiser FFF Survey)

**2011-13**
- Plans followed ACA transitional limits, or just went direct to unlimited
- Providers took cautious note on newfound billing capabilities

**2014**
- $1 million+ claims grow rapidly
- Seemingly as hospitals note there’s no longer a shared “stop” or Medicaid transition

**2015-16**
- Catastrophic claimants continue; $5 million claimants occur for most stop loss writers
- Rare orphan conditions and their treatment have proven funding; Wall Street notes

**2017+**
- Continues unabated and cat claims are still not a focused public/political concern
- Health care reform efforts unsettled, leaving unlimited untouched

# Who Are These Claimants?

- Congenital anomalies, blood disorders and neoplasms are common diagnoses – see largest claim examples in table below
  - Typically less impacted by lifestyle and wellness initiatives
- Other "million dollar" stop loss claimant trends (Sun Life, Book of Business 2014-17, *2018 Research Report*)
  - 2.1% of stop loss claimants but 19.9% of reimbursements
  - They're young: 49% under age 20; 29% of those under age 2
  - Injectables are growing: associated charges for $1M+ claimants increased 80% from 2014 to 2017

| Primary Diagnosis | Total Cost | Age |
|---|---|---|
| Metabolic & Immunity Disorders | $6.7M | 20-39 |
| Hemophilia/Bleeding Disorders | $5.0M | 2-19 |
| Diseases of Arteries, Arterioles & Capill. | $4.1M | <2 |
| Leukemia, Lymphoma and Mult. Myeloma | $3.6M | 2-19 |

Source: Sun Life, *2018 Research Report*, 2014-17 claims data

# Self-Insured? A Swim with Sharks

- Very sizeable health claimants now lurk
  - Over $2M if not $5M in a plan year
  - Member impact aside, these are organizationally impactful (e.g. quarterly financials and earnings)
- Creates a financial risk never envisioned for a self-insured, active employee health plan
  - Ensure the CFO is aware
  - Confirm adequate risk protection

# Opened Market for "Orphan" Therapies

Business The Washington Post 8/4/2016

High prices make once-neglected 'orphan' drugs a booming business

- Orphan Drug Act, 1983
  - Encouraged Pharma to develop drugs for rare diseases otherwise ignored (i.e. "orphans") due to small market – under 200,000 patients
  - Offered 7-year exclusivity and tax credits for ½ of development costs
- Encouraged development, but pre-ACA/2010 health plan dollar limits curtailed potential revenue

# Lifesaving – But at Significant Cost

- Orphan diseases affect small groups of patients
  - But diseases are numerous
  - Many yet to have a regimen

| Orphan Drug Name | Condition | Annual Expense |
|---|---|---|
| Soliris | Blood disorder | $550,000 |
| Spinraza | Muscle disorder | $750,000 yr. 1; $375,000 |
| Ravicti | Urea cycle disorder | $550,000 |
| Alprolix | Factor IX Blood Disorder | $500,000 |
| Cerezyme | Gacuher's Disease | $300,000 |

The Washington Post
BUSINESS
Max's best hope costs $750,000

# Orphans and Others…

- Aside from true "orphans", costly treatments may target cancer, hemophilia and metabolic conditions
- Established drugs may also get recycled under an orphan status on a separate, qualifying condition (infamously done by Martin Shkreli)

| Format | Basis | Example |
|---|---|---|
| Biologics | Living cells, organisms | Soliris – blood disorder |
| Gene Therapy | Use of normal genes to correct faulty | Luxturna – blindness |
| CAR-T | Cell-modification immunotherapy | Kymriah – cancer |

# Deals & Acquisitions Abound!

Shire Opens Door to $64 Billion Sale to Japan's Takeda

The combined entity would be the world's eighth-largest drugmaker

Novartis Bets $8.7 Billion on Gene-Therapy Company

The deal is a bet that at least one drug AveXis is developing to treat spinal muscular atrophy will become a blockbuster

J&J's $30 Billion Biotech Deal Carves Out Drug-Discovery Unit

Deal gives U.S. pharma giant access to Swiss firm's rare-disease portfolio amid competition pressures

**BioMarin Prices Orphan Drug at $702,000, Promises Big Discounts**

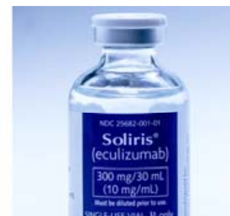
by **Caroline Chen**

April 27, 2017, 6:17 PM EDT

- Pharma prefers to acquire aspiring therapies instead of developing them
- **Pricetags reflect future income streams** – not R&D expense and debt

**When the Patient Is a Gold Mine: The Trouble With Rare-Disease Drugs**

With a flagship treatment that helps fewer than 11,000 people, how is Alexion making so much money?



## Inpatient Hospital Expense Too

- High cost claimants are revenue leaders – and watched closely
  - Especially at teaching hospitals and children medical centers where they often reside
  - No longer limited with lifetime caps
  - Injectables done inpatient can be several times more costly than an outpatient or home infusion setting

*"The CEO carries with him at all times a five-page spreadsheet that's got the 35 kids who are running in excess of $1 million…that is the financial lifeblood of that institution as it is for…all the academic medical centers."*

*- Advisor to a leading University Children's Hospital in California, 2017*

## Accumulation Risk – Large & Ongoing

- As already seen with Factor VIII hemophilia – and looming with ongoing Orphan regimens
  - These claimants create sizeable, long-term, unreserved liabilities
  - Especially if no stop loss at onset (as no one will ever pick it up)
  - Even if stop loss, an underwriter may be able to 'laser'
- In example:
  - 17 year old Factor VIII dependent claimant
  - Annual regimen = $650,000
  - Liability, present value over the next 5 years ≈ $3 million
  - Typically unreserved – despite being a very predictable expense
- CFO reaction: What??!! How much?! How long!? Where's our hedge? (stop loss is one answer)

*If a similar P/C risk exists elsewhere in the firm – it likely already has coverage.*

## Rare + Inpatient = $5 Million +

- An actual episode of care
  - A very rare form of a bleeding disorder
  - Month-long inpatient hospital stay at a not-for-profit system
  - In-network with a leading national PPO
  - One therapy, new to market, life saving and administered inpatient
- Expense
  - Inpatient room per diem was slight – about $200,000 of total
  - Therapy billed at Price x Units: no AWP, no marginal costs
  - Billed: $16.4 million → $9.5 million after contracted discount (41%)
  - "Prompt payment" provision required timely payment to hospital
  - Agreed to a reduced bill by approx. $1 million after plan sponsor negotiation
- Plan Sponsor's Exposure
  - Subject to a $1 million specific – implemented just months earlier
  - Over $7 million reimbursed on a 1st year 12/12 policy with $400,000 in annual premium

*"Thank you for listening to the advice to establish coverage. Great job!"*
*- CEO to VP, Benefits & Compensation*

## A Recap on Claim Severity

- Health care is big business
- ACA's removal of dollar limits further supports high claimants
- Catastrophic claimants can be large and ongoing
- Many are dependent children, often congenital
- Wellness and lifestyle have no real impact
- Pharma is eagerly pursuing orphan regimens, often $100,000s per year (as Wall Street cheers)
- A perfect storm of inpatient hospital, injectable drugs and a rare condition can equal several million dollars – even after leading PPO discounts

# Risk Management Strategies

- Alternate delivery and risk mechanisms are often discussed, but maintaining the status quo seems most prevalent (2018 Aegis Risk Medical Stop Loss Premium Survey)

# Forward Strategies

- Orphan and high dollar diagnoses are hard to prevent or avoid
- Recommendations focus more towards managing, including:
  - How does your plan manage chronic and costly conditions – does any stop loss carrier offer further programs?
  - Confirm clinical support for blood disorders; ask PBM if any programs specific to hemophilia
  - Review your plan and PBM to confirm support of at-home drug infusions
  - Review your stop loss policy to see if gene therapy has limitations or exclusions. Avoid conflicts.
  - Does a provider-reimbursement negotiation and review entity exist?
- ICER (Inst for Clinical & Economic Review) is an entity proactively evaluating the effectiveness of new drug therapies.
  - Many stakeholders are following their lead
  - www.icer-review.org

## Actions? Stop Loss – Build a Fence

- Who should build one?
  - Any plan that cannot withstand a $5 million hit – how will Finance take that?
  - At $10,000 net PEPY, $5 million is 5% of budgeted for 10,000 employees
  - The traditional thought you can outgrow stop loss is outdated and naïve
- How high (e.g. deductible) should I build it?
  - Your organization's own risk tolerance ultimately defines that
  - Some rule of thumbs, if under 5,000 employees:
    - $500,000 to $750,000 annual premium – what level specific creates that?
    - 2.0% to 5.0% of gross health care expenditure → but can vary widely
  - If over 5,000 employees:
    - Identify level that 2 to 3 highest claimants breach
    - Price against the level where perhaps one breaches; find optimal risk transfer
- Most every plan sponsor should consider some type of a fence
  - If you think you're "too big", just get a higher deductible, e.g. $2 million
  - If any thought of dropping, consider explaining that $9.5 million claimant

## What Type of Fence? Not a Picket

- Pursue/Price a No New Laser with Renewal Rate Cap contract
  - Laser: a claimant excluded from stop loss, at placement or renewal
  - Based on premise that insurance covers unknown risk, not known
  - Typically via higher deductible, restrictive claims basis or outright exclusion
- No New Laser at Renewal is just that – evolving claimants remain covered
  - However, without a rate cap, the renewal could be 100% or higher
  - A renewal rate cap, at 45% or 50%, can actually be a very strong deal
  - Does incur as much as a 7% to 10% premium rate load
- With a strong No New Laser with Rate Cap contract, a plan is best protected from accumulation risk of an ongoing claimant
  - As once the claim occurs, it's 'known'. Other underwriters won't take it.
  - But get it while you can – one year forward guarantee is evolving

# Other Attributes of Your Fence

- Confirm or pursue "plan mirroring" amendments
  - Ensures consistency between covered, eligible expenses per your health plan documents and your stop loss contract
  - Minimizes, if not erases, conflict by "clamping on" to the health doc
  - Particularly on "usual, customary & reasonable" (UCR)
  - At highest dollar levels, the basis of UCR can widely vary; become litigated
- Investigate a dividend contract
  - An effective way to "claw back" premium during favorable claim periods
  - Based on an established formula – e.g. loss ratio < 65%
  - Large groups, often previously uncovered, are good candidates
  - May offer as much as 5 to 10% premium refund
  - For the hesitant, makes the decision to get coverage a little more palatable
- Finally…index your ISL deductible to underlying trend at renewal
  - An unchanged deductible incurs a greater, leveraged percent of plan costs over time (i.e. leveraged trend)

# Fences – What About Captives?

- An often elusive and intriguing discussion
  - Bermuda??!! The Caymans?!
- They get a lot of talk and attention – they do sound cool
  - A (complex) vehicle to retain risk in lieu of premium to an insurer
  - Works best for predictable risks – stop loss is not. It's volatile.
  - Organizationally, there may be many such risks; life/disability in benefits
- Where most sensible, there's often another variable
  - An existing property/casualty captive, with the plan sponsor, seeks "outside" risks to maintain its preferred tax status (i.e. "CFO says so")
  - A smaller group transitioning to self-funding is unable to find stop loss
    - Pool with others and gain a "cell" within an existing captive "condo"
    - Offers a lower captive deductible (e.g. $50K) before higher stop loss (e.g. $250K)
    - But…your low claims may be offset by the high claims of your noisy neighbors
- When stop loss premiums are "soft" their value negates, but…

# It's a Risk – Mind the Process

- Stop loss is not an <u>employee</u> benefit. It covers the <u>plan sponsor</u> from the financial variability of self-funding.
- In that aspect, it's much more a property / casualty risk.
  - Which operates fully different from benefit procurement
  - There is no member service or support aspect involved
  - More strictly a financial determination balanced by quality of policy and claims paying ability
- Like Property/Casualty, it behooves to sell the risk to the underwriter
  - The underwriters are a bit more the "pickers and choosers"
  - Share information; describe attributes of your plan (e.g. actual discounts)
  - It is an actively underwritten risk – be inactive at your own expense

# It's a Risk – Mind Disclosure

- Disclosure, as stipulated, of all known high claimants (and/or diagnoses) is a serious, sober process
- Similar to P/C lines, stop loss insures future, unknown risk
  - Ongoing claimants are expected, but outliers will gain notice (see "selling")
  - A single claimant, foreseeable, can be a multiple of annual market premium
  - Lasers frustrate and ensue – focus on minimizing and avoid future
- Ignore or mishandle at your own risk – your advisor too
  - If not disclosed – and should have – it's not getting covered. Blame follows.
  - "No Disclosure" carriers and programs exist – but it still happens; it gets provided and reported; disputes can still ensue.
- Upon review/acceptance of disclosed claims, an underwriter 'firms' the quote/renewal, listing lasers (if any)
  - Sign the Application and send that first month premium!

## The Future

- Are these life-preserving therapies at the projected costs tenable?
  - It perplexes. As the life-preserving aspect is difficult to deny.
  - Will entities like ICER gain further prevalence and guidance on market pricing?
- May rare disease therapies become Medicare eligible, similar to ESRD and kidney dialysis? Or in a public "cat pool"? (likely not)
- Will outcomes-based reimbursement prevail?
  - If the therapy fails, a refund
  - But how long to measure success? Is patient still in population?
- Installment payment plans?
  - Spread one-time injection expense over 60 months?
  - But doesn't a properly constructed insurance policy do that?
- A rare-disease only stop loss at higher specific of $1 million+?
  - May be both sole coverage of a larger plan (e.g. 30,000 ees)..
  - …and a back-stop to "smaller", freeing the risk price from core stop loss

## Three Key Takeaways - Revisited

- Awareness of the financial severity of these claimants
  - Beware their size…and potential to remain ongoing
  - Underlying condition is often congenital or hereditary – and rare
  - Revenue objectives of Wall Street and Pharma may foil effective pricing
- Understanding of risk management approaches
  - Ensure forward strategies with health plan and PBMs
  - At what threshold should any plan "build a fence" to protect itself?
  - Stop loss remains the prevalent approach, but how to improve it
- Discussion of potential pitfalls with stop loss and risk transfer
  - Understand this is not an employee benefit; it's a plan sponsor risk
  - Respect the Disclosure process; its requirements; and its objective
  - What may the future hold for such costly reimbursements?

# With All That Said…

Any questions – please ask!

Ryan Siemers, CEBS
Principal
Aegis Risk LLC
703.778.6520
ryan.siemers@aegisrisk.com
www.aegisrisk.com

# Stop Loss: Specific and Aggregate

**Specific (or Individual)**

- Guards against the volatility of individual high-cost claimants
- The common form of stop loss
- Reimburses claims beyond a specified deductible – as low as $50,000 to as high as $1+ million.
- The contract stipulates the covered claims basis on dates of incurral and/or payment (e.g. 12/15, paid)
- Reimburses expense for an individual contract year (i.e. it's not ongoing)
- Premiums vary widely by deductible

**Aggregate**

- Protects against over-utilization of the entire health plan
- More common with smaller (<1,000 ees), risk-adverse employers
- Reimburses if overall plan expense exceeds a threshold (e.g. 125%)
  - Based on an expected claims rate per covered employee
- Per covered claims basis
- Premiums less, as claims uncommon
- Typically, it augments specific
  - No double indemnity

# Appendix: Stop Loss Coverage
## Key Provisions and Processes

| Provision/Process | Description | Recommended Strategies |
|---|---|---|
| Actively at Work | Coverage only for employees actively at work at onset of coverage – unless waived. | Seek waiver during final Disclosure and acceptance of risk – prior to effective date. |
| Experimental | Medical claims deemed experimental and not eligible for coverage. | Ensure agreement or deference to the underlying medical plan SPD. |
| Aggregating Specific Deductible | A separate plan-wide deductible requiring fulfillment before any individual deductibles. | Lowers premium, but an increase in the plan deductible is simpler & obtains same. |
| Reporting Requirements | Stipulated claim reports, often monthly, required by the stop loss carrier. | Ensure TPA/ASO provides both '50%' and claim detail reports. Ideally with no fees. |
| Change in TPA/ASO | Notification of a change in TPA to stop loss carrier. | Observe. The presence of an approved TPA is an underwriting element. |
| Coverage exclusions | Uncovered expenses (e.g. occupational related, above R&C, from criminal acts). | Ensure agreement or deference to the underlying medical plan SPD. |
| Pharmacy | Coverage of pharmacy expenses. | If elected, ensure reporting if not integrated with medical – many forget! |
| Lasers | Exclusion or placement of a higher deductible on select individuals. | Avoid, but balance their presence with potential reduction in premium. |
| Disclosure | Final process to a 'firm' proposal, where underwriter reviews known high claims. | A key process! Better claims data often means lower premium and no lasers. |

# Appendix: Claim Frequency

**Reported frequency and/or catastrophic claimant dynamics**

- *HM Stop Loss, 5-Year Claims History* (June 2018)

Claims Incidence Per 100,000 Employees

| UW Year | $500,000 | $1,000,000 | $1,500,000 |
|---|---|---|---|
| 2013 | 33.6 | 5.8 | 1.6 |
| 2014 | 35.0 | 7.1 | 2.1 |
| 2015 | 35.1 | 5.8 | 2.1 |
| 2016 | 44.4 | 6.7 | 2.3 |
| 2017 | 55.3 | 9.3 | 3.9 |

- *Sun Life 2018 Stop Loss Research Report* (Spring 2018): Million-dollar+ Claims Summary

| Stop-loss | | | | |
|---|---|---|---|---|
| Percent of stop-loss reimbursements | 15.3% | 20.3% | 23.2% | 19.9% |
| Percent of total claimants | 1.7% | 1.9% | 2.2% | 2.1% |
| **Injectable drugs** | | | | |
| Total paid claims | $10.4M | $10.1M | $22.2M | $18.7M |
| Average paid charges | $193.3K | $129.9K | $234.0K | $219.5K |