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CONTINGENT VALUE RIGHTS

A Drafting Guide for Biopharma M&A

Market Terms · Model Pro-Buyer / Pro-Seller Clauses · Litigation & Regulatory Lessons

Built on a library of all CVR agreements from public-target biopharma acquisitions of $1–25 billion (2015–H1 2026), the controlling Delaware and New York case law, and the 2025–2026 drug-pricing and trade-policy landscape.

July 2026

INTRODUCTION

How to Use This Guide

Contingent value rights ("CVRs") have become a prominent feature of biopharma M&A. In the public-target, $1–25 billion segment, CVRs appeared in under 10% of deals before 2019 but 23–33% of deals in every year since 2023. They let a buyer pay less cash at signing while preserving upside for selling stockholders on a binary clinical, regulatory, or commercial catalyst, and they shift the drafting battleground from price to the fine print of the milestone, the efforts covenant, and the enforcement machinery.

This guide is organized around that fine print. **Part I** sets out what the market actually does, drawn from a library of all CVR agreements executed in public-target biopharma acquisitions from 2015 through H1 2026 ($1–25 billion). **Part II** is the core: a term-by-term drafting analysis with side-by-side pro-buyer and pro-seller model clauses and drafting notes. **Part III** distills the lessons of the recent CVR and milestone litigation — the cases now driving negotiation. **Part IV** addresses the 2025–2026 regulatory overlay (Medicare price negotiation, "most-favored-nation" pricing, and pharmaceutical tariffs) that has the potential to make sales-based milestones materially harder to hit and to measure. **Part V** covers a different animal — the reverse-merger CVR. **Part VI** is a consolidated drafting checklist.

> The model clauses are illustrative formulations synthesized from market precedent and the case law; they are **drafting starting points, not off-the-shelf language**, and should be tailored to the specific asset, milestone, and deal dynamics.

CONTENTS

QUICK REFERENCE

The CVR Negotiation Matrix

Eight provisions decide most of a CVR's value. Each column is that side's opening ask; the last is the authority that gives it teeth. Model language and holdings are in Parts II–IV.

PROVISION	PRO-BUYER ASK	PRO-SELLER ASK	WATCH POINT / AUTHORITY
Efforts standard	Subjective / own-business-judgment standard; express list of decisions that do not breach; "primary purpose" duty only	Objective, payment-disregarding standard, usually benchmarked to the buyer's own "priority products" (occasionally a comparable company)	*SRS v. Alexion* — synergies are no defense; *Himawan* — "due regard to cost" saved the buyer. Part II.C
Milestone definition	Single named approval pathway and indication; hard outside dates; no partial credit	Pathway-agnostic trigger ("approval by any route"); stacked or pro-rata credit; anti-frustration language	*J&J v. Fortis* (Del. 2026): a 510(k)-only milestone allocated pathway risk to holders — no implied-covenant rescue. Part II.D
Net Sales & measurement	GAAP plus buyer's historical methodology; broad deduction basket; U.S.-only measurement	Exclusive enumerated deductions; add-backs for IRA / MFN government pricing actions; audit and true-up	Say expressly that tariffs are COGS, not a Net Sales deduction — the 2025–26 models do. Part IV
Information rights	Annual summary milestone report; no inspection right	Quarterly reporting, books-and-records inspection, independent audit right	*UMB Bank*: an inspection demand opened the $6.4B Celgene CVR fight. Part II.E
Trustee & holder standing	No-action clause; meaningful acting-holder thresholds; precise holder mechanics bar unauthorized suits	Express beneficial-holder rights to direct and replace the trustee and to sue	*UMB Bank*: defective appointment cost holders the case in 2024; cured and revived Dec. 2025. Part II.E
Fraud & anti-reliance	Mutual, unmistakable anti-reliance confining claims to the contract	Preserve intentional-fraud claims — Delaware will not enforce a waiver of its own fraud	*J&J v. Fortis*: fraud verdict affirmed where disclaimers were not airtight. Part III
Disputes, forum & fees	Independent-accountant expert determination, "final and binding" absent manifest error	Delaware law, Chancery forum, jury-trial waiver; fee-shifting for holder enforcement	Listed, indenture-style CVRs (Celgene, GCVRZ) draw federal trustee litigation instead. Part II.F
Tax & transferability	Non-transferable, unlisted CVR; clear withholding mechanics	Specified intended treatment — merger consideration (§ 483 / OID), not compensation	State the intended treatment and confirm with tax counsel — characterization is not automatic. Part II.F

BOTTOM LINE Anchor every ask to a model clause (Part II) and a decided case (Part III) — leverage, not preference, sets where each provision lands (Part I).

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CVRS IN THE MARKET

What the Data Show

A library of all CVR agreements from public-target biopharma acquisitions, 2015 through H1 2026 ($1–25 billion upfront equity value).

PART I · THE DATA

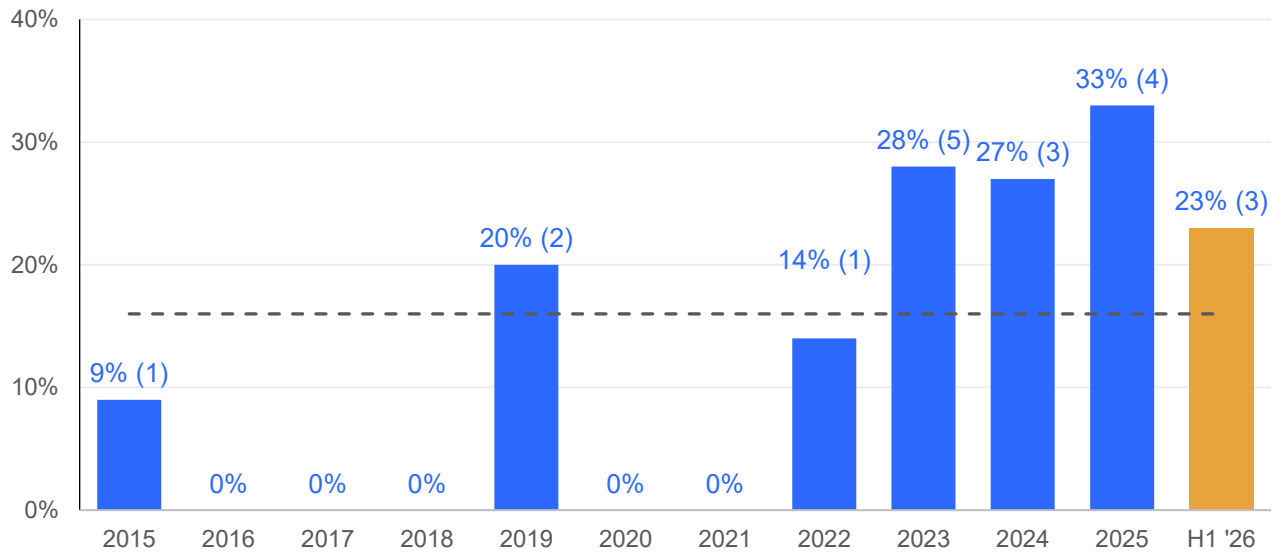
CVRs in the Market

KEY POINTS

- CVR usage has gone mainstream: from a rarity pre-2019 to roughly a quarter to a third of $1–25B public-target biopharma deals each year since 2023 (19 of 116 deals across the full period).
- The efforts covenant is the single most negotiated and most litigated term; most recent agreements settle on an objective, payment-disregarding standard — usually benchmarked to the buyer's own priority products.
- Regulatory-approval milestones dominate (11 of 19 agreements); "filing/acceptance" milestones are the easiest to hit; net-sales milestones are recent (3 deals / 5 milestones, all 2025–2026) and carry the most measurement risk.
- CVRs are almost always non-transferable, book-entry, Delaware-law instruments with a rights agent; "Acting Holder" thresholds to direct enforcement cluster at 35–50% of CVRs.

The rise of the CVR

Share of $1–25B public-target biopharma acquisitions with a CVR, by year (deal count in parentheses). Dashed line = 2015–H1 2026 average (16%). A 0% bar means qualifying deals were announced that year but none included a CVR. Source: Gibson Dunn Biopharma M&A Deal Index — 116 announced deals meeting the size and sector criteria above, 2015–H1 2026; 19 included an acquisition-side CVR (acquisition-consideration CVRs only).



Anatomy of the CVR Agreement Library

TERM	WHAT THE MARKET DOES
Consideration	One non-transferable CVR issued per target share, alongside cash (occasionally cash + acquirer stock). CVRs are book-entry (DTC), unlisted, and carry no voting, dividend, or interest rights.
Milestone type	Regulatory approval dominates — 11 of 19 agreements, 15 of 31 milestone instances. Other types: net-sales (5 instances), regulatory filing/acceptance (4), clinical/development (4), first commercial sale (2), PRV issuance (1). Several agreements stack milestone types.
Per-CVR value	Ranges widely — from $0.30/ordinary share (Gracell) to $12.00 (Mirati) and a multi-tranche $20+/share (Metsera). CVR value is typically 10–30% of total deal value.
Structure	Both “all-or-nothing” (Celgene/BMS, outside the $1–25B library — all three approvals or nothing) and “severable per-milestone” (most). Severability materially changes risk.
Efforts covenant	Spectrum, buyer- to holder-favorable: express “No Obligation” (Clementia, Chinook, Arcellx) › subjective own-portfolio standard, no payment carve-out (Blueprint, Centessa) › objective but silent on the payment (Dyax, Mirati) › objective that factors the payment in (Akero, Metsera) › objective that disregards the payment, usually benchmarked to the buyer’s own priority products (10 agreements: Alder, Zogenix, Amryt, CinCor, Gracell, Inhibrx, 89bio, Apellis, Fusion, Poseida; Amryt adds a prescriptive, inward-facing overlay).
Acting Holder	Threshold to direct the Rights Agent / sue for all holders: 40% is modal (7 — CinCor, Gracell, Fusion, Poseida, 89bio, Metsera, Centessa); a majority (4 — Alder, Clementia, Zogenix, Amryt); 35% (Dyax, Blueprint); 32.5% (Apellis); 45% (Chinook); 50% (Mirati); Inhibrx names a holder replaceable at 26%; Akero and Arcellx have none (20% block on adverse amendments only).
Transferability	Non-transferable except customary permitted transfers (death, operation of law, DTC nominee-to-beneficial). None were listed/tradeable (contrast the older Celgene “CELG RT” and Genzyme “GCVRZ”).
Reporting	Most grant only a books-and-records covenant; a minority grant real milestone-status reporting (Amryt annual; Alder notices; Inhibrx on request; Blueprint annual to Specified Holders). Audit rights are rare (Apellis is the exception).
Governing law / forum	Delaware law, Delaware Court of Chancery exclusive forum, express jury-trial waiver, no arbitration — with foreign-parent/scheme deals the main exception (Amryt used ICC arbitration).
Tax	Share-based CVRs treated as additional (deferred/contingent) merger consideration with imputed interest under § 483; CVRs on options/RSUs treated as compensation run through payroll.

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II

TERM-BY-TERM DRAFTING

Model Clauses

Each subpart states the drafting tension, then gives side-by-side pro-buyer and pro-seller formulations with a drafting note. The efforts covenant (II.C) is the crux and is treated at greatest length. The model clauses are illustrative starting points — not off-the-shelf language — and must be tailored to the asset, the milestone, and the deal.

Term-by-Term Drafting

A Milestone definition and structure

Market practice. Regulatory-approval milestones appear in 11 of the 19 surveyed agreements (15 of 31 individual milestones); "filing/acceptance" milestones (Mirati's FDA acceptance of the MRTX1719 NDA; CinCor's regulatory submission) are easier to achieve and less manipulable. "All-or-nothing" structures (Celgene/BMS, outside the $1–25B library) concentrate risk on a single date; most deals use severable, per-milestone payments.

PRO-BUYER / ACQUIRER	PRO-SELLER / CVR HOLDERS
Milestone = FDA approval of [Product] for [specific indication] via [specified pathway] on or before [hard outside date]. The CVRs pay only if **ALL** Milestones are achieved by their Target Dates; if any is missed, the Agreement terminates and no payment is due. No extension for regulatory delay.	Each Milestone is **SEVERABLE** and pays independently. "Approval" includes any successor or alternative regulatory pathway that yields a substantially similar result and is not materially more burdensome in time, cost, or effort. Outside dates are tolled for delays outside the Company's reasonable control (FDA scheduling, government shutdown).

Drafting note. After *Johnson & Johnson v. Fortis* (Del. Supr. 2026), a milestone tied to a **named** pathway allocates the risk of a pathway change to the holders — the implied covenant will **not** supply an alternative-pathway duty. Sellers must build alternative/successor-pathway language expressly; buyers who want the risk on the seller keep the milestone closed-ended and pathway-specific. Prefer filing/acceptance milestones where a clean, early payout is the goal.

B Consideration, transferability, and instrument mechanics

Market practice. All surveyed CVRs are non-transferable, book-entry, and unlisted. Transferable/listed CVRs (older Celgene "CELG RT", Genzyme "GCVRZ") create securities-law, disclosure, and trustee-standing complexity and have fallen out of favor for milestone CVRs.

PRO-BUYER / ACQUIRER	PRO-SELLER / CVR HOLDERS
CVRs are non-transferable (except by will, intestacy, or operation of law), non-certificated, and unlisted; they confer no voting, dividend, equity, or interest rights and represent only the contingent contractual right to a Milestone Payment. Abandonment to Parent permitted.	Same non-transferability, **plus** express permitted transfers for fund/partnership pro-rata distributions and the depositary's distribution to ADS holders; confirm CVRs pass to beneficial holders through DTC without further action, and that a Milestone Payment, once due, is a fixed obligation not subject to set-off.

Drafting note. Non-transferability, together with the other structural characteristics reflected in SEC no-action precedent, supports the position that registration and ongoing reporting are not required. If tradeable CVRs are used, the trustee/standing mechanics in II.E become critical (see the Celgene/BMS standing saga).

C The efforts covenant — the heart of the CVR

Every recent milestone case turned on two questions: (i) is the efforts benchmark **objective** (a hypothetical comparable company) or **inward-facing** (the buyer's own priority products), and (ii) may the buyer weigh the cost of the milestone payment itself? Delaware enforces the exact words chosen; the implied covenant will not rescue a risk the contract allocated.

Market practice. Of the 19 agreements, 10 (53%) use an objective standard that expressly **disregards** the milestone payment — usually benchmarked to the buyer's own priority products (Alder, Zogenix, Amryt, CinCor, Gracell, Inhibrx, 89bio, Apellis, Fusion, Poseida; Amryt layers prescriptive, inward-facing duties on top); 2 **factor the payment in** (Akero, Metsera); 2 are objective but **silent** on the payment (Dyax, Mirati); 2 are **subjective**, benchmarked to the buyer's own portfolio with no carve-out (Blueprint, Centessa); and 3 impose **no efforts covenant** at all (Clementia, Chinook, Arcellx).

FORMULATION SPECTRUM · MOST → LEAST BUYER-FAVORABLE

FORMULATION	EFFECT	EXAMPLE(S)
"Sole and absolute discretion" + only a "primary purpose" anti-frustration duty; no affirmative efforts	Most buyer-favorable; seller must prove dominant bad purpose	*Fortis v. Medtronic*; Arcellx / Chinook / Clementia
Subjective CRE measured against the buyer's **own** investment metrics; cost of payment considered	Buyer-favorable	Blueprint; Centessa
Objective CRE benchmarked to a comparable company, **with** "due regard to cost"	Buyer can weigh the milestone cost / decline losing programs	*Himawan v. Cephalon*; Dyax; Mirati; Akero; Metsera
Objective CRE / Diligent Efforts, comparable company, disregarding the milestone payment	Market center; walls off the buyer's own agenda	CinCor, Gracell, Inhibrx, 89bio, Apellis, Fusion, Poseida
Inward-facing "priority product" standard + prohibition on considering cost + prescriptive duties	Most seller-favorable	*J&J/Auris*; Amryt

The model formulations, and the drafting note on neutralizing the *Cephalon* "due regard to cost" defense, continue on the following page.

MODEL EFFORTS COVENANTS

PRO-BUYER / ACQUIRER	PRO-SELLER / CVR HOLDERS
Parent shall have **sole and absolute discretion**, in its good-faith business judgment, over all matters relating to the [Product], and shall have **no obligation** to take any action to achieve any Milestone; provided that Parent shall not act for the **primary purpose** of avoiding a Milestone Payment. Parent may (i) operate its business and any competing product in its own interest, (ii) discontinue, deprioritize, out-license, or divest the [Product], and (iii) take into account the cost of the Milestone Payments. The enumerated factors create no efforts obligation.	Parent shall use **Diligent Efforts** to achieve each Milestone — efforts at least commensurate with those Parent devotes to its **own** products of similar potential and stage that are among Parent's priority products, **determined without taking into account** (x) any Milestone Payment or its effect on the economics of the [Product] or (y) any competing product. Diligent Efforts include maintaining an appropriate sales force and development budget; making the [specified filing] by [date]; appealing any adverse decision; and **not** discontinuing, deprioritizing, or divesting the [Product] or favoring a Competing Product.

Drafting note. The single most valuable seller clause is the **"without taking into account the Milestone Payment"** carve-out — it neutralizes the *Cephalon* "due regard to cost" defense; note the pro-seller model deliberately blends the two most seller-favorable tiers of the p. 9 spectrum (inward-facing "priority products" benchmark + objective payment-disregard carve-out). The single most valuable buyer clause is an express statement that enumerated business decisions do **not** breach — it converts hindsight efforts review into express risk allocation, and a bare "primary purpose" anti-frustration duty (*Fortis v. Medtronic*) imposes an "unusually heavy" pleading burden on holders — the buyer high-water mark. Note *SRS v. Alexion*: an objective standard barred the buyer from justifying a program's termination by pointing to merger synergies — document commercial decisions to the contractual factors in real time.

D Milestone guardrails: anti-deprioritization & anti-favoritism

Market practice. Holder-protective covenants beyond the efforts standard appeared mainly in recent, competitive deals (Apellis's affirmative "maintain a sales force / work force" overlay). Buyers push back with enumerated permitted actions and defined carve-outs (no additional trials, no loss of orphan status, capped pre-clinical spend).

PRO-BUYER / ACQUIRER	PRO-SELLER / CVR HOLDERS
Nothing limits Parent's right to make portfolio, pipeline, pricing, personnel, or capital-allocation decisions. Parent has no obligation to (i) conduct any additional clinical trial not required by the [specified] pathway, (ii) spend more than $[__] on the [Product], or (iii) maintain any orphan/exclusivity status. Compliance with law (including any government price program) is never a breach.	Until the earlier of achievement or expiration, Parent shall **not** discontinue, deprioritize, wind down, or divest the [Product] or its program; reduce the dedicated sales force or development budget below [baseline]; or devote materially greater resources to a Competing Product. Parent shall maintain the [Product]'s regulatory exclusivity and make the filings necessary to pursue each Milestone.

Drafting note. Pair any "compliance with law is not a breach" carve-out (buyers legitimately need it for MFN/IRA compliance — see Part IV) with a **Net-Sales hold-harmless** so lawful price concessions do not silently defeat a sales milestone.

E "Acting Holder" threshold and holder standing

Market practice. Enforcement is centralized: individual holders are barred from suing except to collect an already-determined, unpaid amount; the "Acting Holders" (or the Rights Agent at their direction) hold the sole enforcement right. 40% is the modal threshold (7 — CinCor, Gracell, Fusion, Poseida, 89bio, Metsera, Centessa); others are a majority (Alder, Clementia, Zogenix, Amryt), 35% (Dyax, Blueprint), 32.5% (Apellis), 45% (Chinook), or 50% (Mirati); Inhibrx names an Acting Holder replaceable at 26%; Akero and Arcellx have none — only a 20% block on adverse amendments.

PRO-BUYER / ACQUIRER	PRO-SELLER / CVR HOLDERS
"Acting Holders" means Holders of a **majority** of the outstanding CVRs. Only the Acting Holders may direct the Rights Agent or institute proceedings; no individual Holder may sue except to collect a Milestone Payment finally determined due and unpaid. The Rights Agent acts only on written direction and with indemnity/funding from directing Holders.	"Acting Holders" means Holders of **[20–25]%** of the outstanding CVRs — **including beneficial owners** holding through DTC/Cede & Co., who may direct the Rights Agent, remove/appoint a successor Rights Agent, and institute proceedings without a separate DTC omnibus proxy. The Rights Agent shall enforce upon such direction; reasonable enforcement costs are borne by [Parent / the CVR proceeds].

Drafting note. This is not boilerplate. In *UMB Bank v. Bristol-Myers Squibb*, a ~$6.4B CVR claim was initially dismissed for lack of standing (Sept. 2024) because the trustee had been appointed by **beneficial** holders while the **registered** holder (Cede & Co.) held 99%+ of the CVRs and had never approved the appointment. Only after the beneficial holders obtained proxies from the registered holder and reconfirmed the appointment did the court hold (Dec. 2025) that the trustee had been validly installed, reviving the claim more than a year later (see Part III). For any registered/DTC-eligible CVR, expressly empower beneficial holders to direct and replace the trustee and to sue, and set the thresholds and holder class with precision — precision that equally protects the buyer by foreclosing unauthorized or duplicative holder suits.

F Amendments, reporting, dispute resolution, and tax

Amendments

Two-tier is universal: ministerial/non-adverse amendments without holder consent; materially adverse amendments require the consent of the Acting Holders (or a majority, or — Apellis — a 75% supermajority for the most sensitive changes and voluntary termination).

Reporting, records, and audit

Most agreements give holders only a books-and-records covenant. Sellers should push for periodic (at least annual) milestone-status/efforts reporting and audit rights — courts credit contemporaneous documentation over post hoc rationales. Amryt (annual status statements) is the holder-protective model.

Dispute resolution

Delaware law, Court of Chancery exclusive forum, and an express jury-trial waiver are standard across this library's unlisted acquisition CVRs; the listed, trustee-administered Celgene CVR (*UMB Bank*) was litigated in the S.D.N.Y., not Chancery. Foreign-parent/scheme deals sometimes use arbitration (Amryt: ICC). For net-sales milestones, add an independent-accountant **expert determination**, "final and binding" absent fraud or manifest error, and address fee-shifting.

Tax

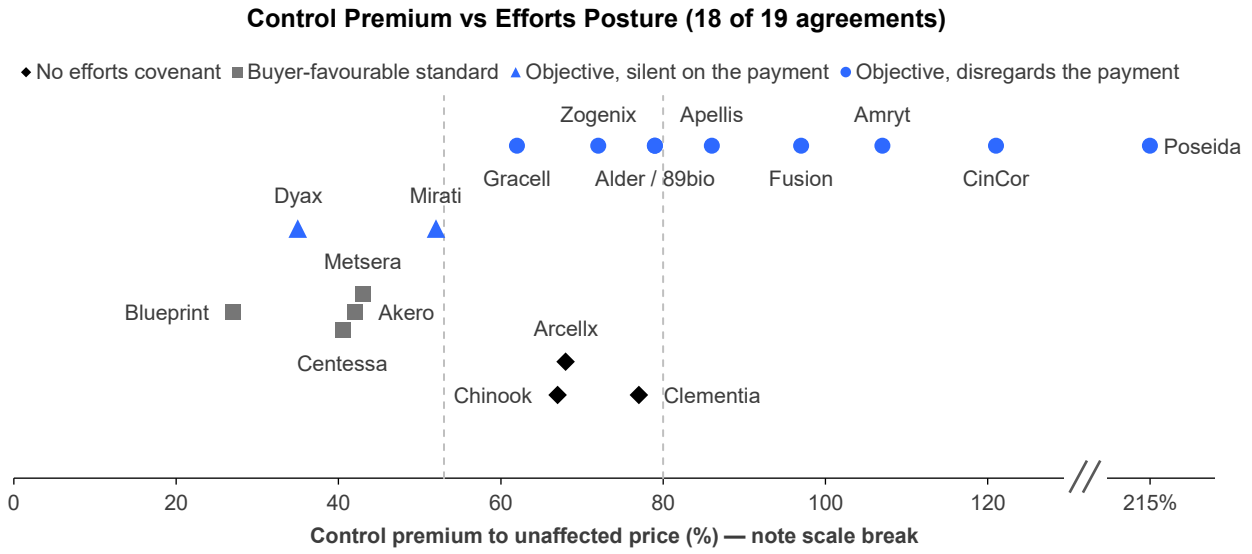
Specify that share-based CVRs are **intended** to be treated as additional merger consideration (open-transaction/installment treatment, imputed interest under § 483 / OID), and that CVRs issued on options/RSUs/PSUs are compensation subject to payroll withholding and § 409A structuring. The characterization is the parties' intended position, not automatic — confirm it with tax counsel and spell out withholding mechanics.

G Bargaining power and term posture: a Deal Leverage Index

Which posture prevails is a function of bargaining power. As a proxy we use the deal's **control premium** to the target's unaffected share price — what the buyer paid to win the asset. Ranking all surveyed deals with a disclosed premium (CVR and non-CVR alike) gives three tiers: **low** (below ~53%; buyer-favorable), **mid** (~53–80%), and **high** (above ~80%; seller-favorable). The median across the 18 CVR deals with a disclosed premium is 70%. Posture tracks leverage only loosely: disregard-the-payment agreements median 86% against 41% for buyer-favorable standards, while the three with no efforts covenant sit at 68%.

Deal Leverage Index – Observed Relationship Between Premium and Efforts Posture

Eighteen of the agreements by efforts posture (see legend). Dashed lines mark premium tertile cut-points; premiums as of the initial announced transaction (topping bids tend to carry forward contract terms negotiated with the first-announced transaction). Inhibrx omitted.†



† Inhibrx is omitted because no comparable premium exists. Sanofi's $30.00 per share in cash was below Inhibrx's $33.33 unaffected close on 22 January 2024; holders also received one New Inhibrx share per four Inhibrx shares — a separately listed company funded with $200 million and the retained non-101 pipeline. Its efforts covenant is among the most holder-protective in the library.

LEVERAGE TIER	WHAT THE BUYER CAN EXPECT	WHAT THE SELLER CAN EXPECT
Low (< ~53%) buyer leverage	No-obligation or subjective efforts; discretion to weigh the milestone cost; majority acting-holder threshold; all-or-nothing tolerated	A CVR at all; a bare "primary purpose" anti-frustration floor
Mid (~53–80%) balanced	Objective, cost-neutral CRE (own "priority products"); ~40–50% acting-holder threshold	Payment-disregard carve-out; severable per-milestone payments; books-and-records
High (> ~80%) seller leverage	Objective CRE with a strict payment-disregard carve-out at most	Inward-facing / priority-product efforts; anti-deprioritization covenants; low (25–35%) acting-holder threshold; periodic reporting / audit rights

Drafting note. The relationship is a tendency, not a formula. All three agreements with no efforts covenant (Chinook +67%, Arcellx +68%, Clementia +77%) sit in the mid tier, not the low tier the index predicts. Metsera is plotted at 43%, the premium on Pfizer's first signed agreement; the topping amendment then raised the cash but replaced the CVR form outright — deleting a $1.5bn spend commitment and cutting the cap to $20.65. Premium alone does not predict the covenant.

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III

LITIGATION-DRIVEN DRAFTING LESSONS

The cases now driving negotiation

Words control; equity does not rescue. The efforts benchmark and the treatment of milestone cost decide most cases.

PART III · LITIGATION

Litigation-Driven Drafting Lessons

KEY POINTS

- **Words control; equity does not rescue.**
  The implied covenant is a narrow gap-filler, unavailable for foreseeable, allocated risks (J&J v. Fortis, 2026).
- **Procedure is substance.**
  For public CVRs, trustee / "acting holder" standing can dispose of a multibillion-dollar claim before the merits (UMB Bank v. BMS).
- **Benchmark & cost drive outcomes.**
  "Disregard the payment" = pro-seller; "due regard to cost" or broad discretion = pro-buyer.
- **Anti-reliance is the fraud firewall.**
  Clear contractual representation by the party asserting fraud that it is not relying on extra-contractual statements (J&J v. Fortis).

CASE	COURT / YEAR	RESULT	DRAFTING TAKEAWAY
UMB Bank v. Bristol-Myers Squibb (Celgene)	S.D.N.Y., 2021–26 (live)	Dismissed Sept. 2024 (trustee standing); revived Dec. 2025 after cure — ~$6.4B all-or-nothing CVR (liso-cel missed by ~36 days) proceeds on "Diligent Efforts"	Draft trustee/acting-holder standing for beneficial owners; avoid all-or-nothing tied to a single hard date
Johnson & Johnson v. Fortis (Auris)	Del. Ch. 2024 / Del. Supr. Jan. 2026	~$1B; efforts breach + fraud affirmed; holders' implied-covenant win reversed (Milestone 1, ~$300M vacated)	Inward-facing "priority product" + no-cost-consideration covenant is potent for sellers; implied covenant won't supply an alternative pathway; anti-reliance must be mutual
SRS v. Alexion (Syntimmune)	Del. Ch. 2024 (liability); June 2025 (damages)	Buyer breached CRE by deprioritizing the asset for merger synergies (~$220M including interest)	An objective "comparable-company" standard bars importing the buyer's own synergy/portfolio agenda
Himawan v. Cephalon (Ception)	Del. Ch. Apr. 2024 (aff'd Del. 2025)	Buyer wins	"Due regard to cost" + "complete discretion" let the buyer weigh the milestone cost and decline a losing indication; CRE ≠ best efforts
Fortis v. Medtronic (Companion Medical)	Del. Ch. July 2024 (aff'd Del. 2025)	Buyer wins (dismissed)	"Sole and absolute discretion" + only a "primary purpose" anti-frustration duty = minimal buyer exposure
Genzyme/Sanofi CVR (GCVRZ) holder litigation	S.D.N.Y.; settled $315M (2019); no merits ruling	Settled after early rulings gave "teeth" to the diligent-efforts covenant — no adjudicated holding	Cautionary public-CVR "go-slow" fact pattern — trial-design, submission timing, and favoring a competing product are litigable; settled, no merits precedent

Synthesis: what each side seeks after the recent cases

Buyers seek

(post-*Medtronic* and *Cephalon*) broad discretion, a bare "primary purpose" duty, an outward "comparable company" benchmark with cost sensitivity, express permission to consider the earnout cost and synergies, closed-ended pathway-specific milestones, mutual anti-reliance, and Delaware forum / jury waivers with expert determination for computational milestones.

Sellers seek

(post-*J&J* and *Alexion*) an affirmative (ideally inward-facing) CRE/Diligent-Efforts covenant that disregards the milestone payment, flat prohibitions on named adverse actions, anti-deprioritization / anti-favoritism covenants, express alternative/successor-pathway language, robust reporting and audit rights, low acting-holder thresholds with beneficial-holder standing, and preservation of fraud remedies.

The throughline

Across every recent decision, the court enforced the words the parties chose and declined to use equity to re-allocate a risk the contract had already assigned. The negotiation is therefore won or lost at the drafting table: name the benchmark, decide the treatment of the milestone payment, allocate regulatory-pathway risk expressly, and get the enforcement/standing plumbing right before signing.

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IV REGULATORY OVERLAY

MFN, IRA & Tariffs vs. Sales-Based CVRs

Three 2025–2026 policy vectors squeeze sales-based milestones — MFN pricing and IRA negotiation compress US net sales, while tariffs compress margins — making milestones harder to hit and to measure unless the drafting allocates the risk.

PART IV · REGULATORY

Regulatory Overlay: MFN, IRA & Tariffs

KEY POINTS

- Three policy vectors squeeze sales-based milestones: MFN pricing (EO 14297) and IRA Medicare negotiation (first 10 prices effective Jan. 1, 2026) compress US net sales; § 232 tariffs (0–100%, April 2026) compress margins — all new and legally contested.
- Tariffs are a COGS/margin event, not a Net-Sales deduction — an argument for anchoring milestones to net sales rather than profit metrics.
- The most consequential choice: whether MFN/IRA price cuts and mandatory rebates deduct from "Net Sales" (buyer-favorable) or are added back / benchmarked (seller-favorable).
- Prefer or front-load regulatory-approval and first-commercial-sale milestones (policy-insulated); treat sales milestones as upside with realistic, worldwide, cumulative thresholds.

In the recent dataset, the 2025–2026 sales-milestone CVRs (89bio, Arcellx, Apellis) **deduct** government/statutory rebates from Net Sales — meaning, by default, the CVR holder bears the drug-pricing-policy risk. The "Net Sales" definition should address each policy vector expressly rather than inherit it by a "consistent with GAAP" default.

POLICY ITEM	BUYER-FAVORABLE (DEDUCT → LOWER NET SALES)	SELLER / HOLDER-FAVORABLE (ADD BACK)
IRA Maximum Fair Price	Count covered units at the negotiated (reduced) price	Measure covered units at a pre-MFP reference price, or add back the MFP delta
MFN / government-benchmarked cuts	Deduct (lower realized price flows through)	Add back government-mandated reductions; gross-up to a defined benchmark
Mandatory statutory rebates	Deduct as a Net-Sales reduction	Exclude statutory/mandatory rebates from deductions (distinguish from commercial rebates)
Section 232 tariffs	Typically not applicable to Net Sales (a COGS item); buyer may seek deduction from Net Sales.	Should be excluded from the Net Sales definition and treated as a COGS input.

Model "Net Sales" treatment for a sales-based milestone

PRO-BUYER / ACQUIRER	PRO-SELLER / CVR HOLDERS
"Net Sales" = gross amounts invoiced for arm's-length third-party sales, less deductions consistent with GAAP and Parent's historical methodology (for the avoidance of doubt, excluding tariffs and customs duties, which are cost-of-goods items and not Net Sales deductions), **including** all rebates, chargebacks, and discounts paid to or mandated by any Governmental Body (Medicare/Medicaid, IRA maximum fair price and inflation rebates, Part D manufacturer discount, MFN or any government-benchmarked price, and any successor program). US-only measurement; single-calendar-year threshold.	"Net Sales" as defined, **provided** that solely for measuring the Milestone, (i) units subject to an IRA maximum fair price or any government-mandated/benchmarked reduction (including under EO 14297 or any successor program) are counted at a Reference Price of $[__]; (ii) mandatory statutory rebates/discounts are **not** deducted; (iii) measurement is **worldwide and cumulative** over a rolling period, at a fixed FX convention; and (iv) compliance with any such law is not a breach, but shall not reduce Net Sales below the hold-harmless benchmark.

Drafting note. Because EO 14297, CMS's proposed "GLOBE" and "GUARD" most-favored-nation rebate models for Medicare Parts B and D (Dec. 2025), and the Section 232 proclamation are new and legally contestable, define policy triggers by **effect/category** ("any government-mandated or -benchmarked price reduction … or any successor or similar program") so the risk allocation survives an injunction or a repeal-and-replace. Pair the buyer's legitimate "compliance with law is not a breach" carve-out with the seller's Net-Sales hold-harmless — the buyer stays free to comply with MFN/onshoring deals while the milestone **measurement** is neutralized for the resulting price cut.

EO 14297

"Most-favored-nation" drug pricing executive order, May 2025 — benchmarks US prices to the lowest paid by comparable nations. New and legally contested.

Jan. 1, 2026

First 10 IRA-negotiated Medicare maximum fair prices take effect — a CMS-estimated ~22% average net reduction, varying by drug and rebate structure.

0–100%

Section 232 pharmaceutical tariff range announced April 2026 — a cost-of-goods event affecting margin, not top-line Net Sales; legal challenges pending.

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V A DIFFERENT ANIMAL

Reverse-Merger CVRs

A structurally different instrument: a pre-closing dividend to a public company's own legacy stockholders, paying on the disposition of legacy assets.

PART V · REVERSE-MERGER CVRS

A Different Animal

The CVRs analyzed above are **acquisition CVRs** — contingent consideration paid by a buyer to a target's selling stockholders on a forward-looking milestone. A structurally different CVR appears in life-sciences **reverse mergers**, where a struggling public company merges a private operating company into itself and, as part of the deal, issues a CVR as a pre-closing dividend **to its own legacy stockholders**. Gibson Dunn maintains a separate deal library of these instruments (2020–2026).

DIMENSION	ACQUISITION CVR (THIS GUIDE)	REVERSE-MERGER CVR
Who receives it	Target's selling stockholders in a change-of-control acquisition	The legacy public company's own pre-closing stockholders, by dividend
What it pays on	A forward milestone the buyer must pursue (approval / sales) for an acquired product	Net proceeds from the disposition/monetization of the legacy company's pre-merger assets, cash, or tax attributes
Core covenant	Buyer's efforts to achieve a milestone	Combined company's (often time-limited) efforts to dispose of / monetize the legacy assets and distribute proceeds
Risk driver	Clinical/regulatory/commercial success + buyer diligence	Whether a third party will buy/license the shelved legacy asset within the disposition period
Litigation profile	Efforts-covenant and standing disputes (Part III)	Disposition-period, proceeds-calculation, and expiration disputes

The drafting overlap is real — both use a rights agent, non-transferability, acting-holder/enforcement mechanics, and (Part II.F) amendment, dispute, and tax provisions. But the reverse-merger CVR's value turns on the **disposition mechanics and the length of the monetization window**, not on an efforts covenant to advance a product. Treat the two as related but distinct instruments.

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VI

DRAFTING CHECKLIST

Eleven decisions to make on purpose

A consolidated, negotiation-ready checklist drawing on Parts I–V.

PART VI · CHECKLIST

Drafting Checklist

1 Pick the milestone metric deliberately: approval / first-commercial-sale (policy-insulated) vs. net-sales (policy-exposed). Consider a blended structure; front-load the near-term de-risking milestone.

2 Structure severable, per-milestone payments unless there is a deliberate reason for all-or-nothing; avoid concentrating the entire payout on a single hard date.

3 Set the efforts benchmark (objective comparable-company vs. inward-facing priority-product) and state whether the buyer may consider the milestone cost — do not leave it to silence.

4 For sellers: add the "without regard to the Milestone Payment" carve-out and flat prohibitions on discontinuation/deprioritization/favoritism; for buyers: enumerate permitted business actions that do not breach.

5 Draft expressly for regulatory change (alternative/successor-pathway language) — do not rely on the implied covenant.

6 Define "Acting Holders", the threshold (sellers 20–35%; buyers majority), and — for registered/DTC CVRs — beneficial-holder standing and trustee appointment/removal mechanics.

7 For net-sales milestones: define "Net Sales" surgically; expressly allocate IRA MFP, MFN/government-benchmarked cuts, and mandatory statutory rebates; confirm tariffs are not a deduction; choose worldwide + cumulative measurement and fix FX.

8 Pair any "compliance with law is not a breach" carve-out with a Net-Sales hold-harmless benchmark.

9 Add periodic milestone-status reporting and audit/records rights; for computational milestones, an independent-accountant expert determination final and binding absent manifest error, with fee-shifting addressed.

10 Use mutual, unmistakable anti-reliance to bar extra-contractual fraud claims — but Delaware will not enforce a waiver of intentional fraud in the contract itself; Delaware law, Chancery forum, jury-trial waiver.

11 Specify the intended tax treatment (additional merger consideration + § 483 imputed interest; compensation / § 409A for equity-award CVRs) and withholding mechanics.

THE BOTTOM LINE

A CVR is only as good as its milestone, its efforts covenant, and its enforcement plumbing. Name the benchmark, decide the treatment of the milestone payment and government price cuts, allocate pathway risk expressly, and get standing right — before signing.

ABOUT GIBSON DUNN

Life Sciences M&A

Gibson, Dunn & Crutcher's Life Sciences and Mergers & Acquisitions practices advise acquirers, targets, and their boards and financial advisors on public and private biopharmaceutical transactions, from tender offers and one-step mergers to CVR structures and cross-border schemes of arrangement. We combine transactional depth with market-leading regulatory, capital markets, and litigation capabilities.

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APPENDIX

Surveyed CVR Agreements (2015 – H1 2026)

Every CVR agreement executed in an acquisition of a U.S.-listed biopharma target with an upfront equity value of $1–25 billion, announced January 1, 2015 through June 30, 2026 — the 19-agreement library underlying the Part I statistics. All 19 were re-verified against the filed record in July 2026.

#	Announced	Acquirer / Parent	Target	Upfront ($B)	Incl. CVR ($B)	Max CVR / Sh.	Milestone Type(s)
1	Nov. 2015	Shire	Dyax	5.90	6.50	$4.00	Reg. approval
2	Feb. 2019	Ipsen	Clementia Pharmaceuticals	1.04	1.31	$6.00	NDA acceptance
3	Sept. 2019	Lundbeck	Alder BioPharmaceuticals	1.75	1.95	$2.00	Reg. approval
4	Jan. 2022	UCB	Zogenix	1.70	1.90	$2.00	Reg. approval
5	Jan. 2023	Chiesi	Amryt Pharma	1.25	1.48	$2.50 / ADS	Approval + PRV
6	Jan. 2023	AstraZeneca	CinCor Pharma	1.30	1.80	$10.00	NDA/MAA filing
7	June 2023	Novartis	Chinook Therapeutics	3.20	3.50	$4.00	Reg. approval ×2
8	Oct. 2023	Bristol Myers Squibb	Mirati Therapeutics	4.80	5.80	$12.00	NDA acceptance
9	Dec. 2023	AstraZeneca	Gracell Biotechnologies	1.00	1.20	$1.50 / ADS	Reg. approval
10	Jan. 2024	Sanofi	Inhibrx	1.70	2.20	$5.00	Reg. approval
11	March 2024	AstraZeneca	Fusion Pharmaceuticals	2.00	2.40	$3.00	NDA acceptance
12	Nov. 2024	Roche	Poseida Therapeutics	1.00	1.50	Up to $4.00	Dev. ×2 + 1st sale
13	June 2025	Sanofi	Blueprint Medicines	9.10	9.50	$6.00	Dev. + approval
14	Sept. 2025	Roche	89bio	2.40	3.50	$6.00	1st sale + net sales ×2
15	Sept. 2025	Pfizer	Metsera	7.60	10.00	$20.65	Dev. + approval ×2
16	Oct. 2025	Novo Nordisk	Akero Therapeutics	4.70	5.20	$6.00	Reg. approval
17	Feb. 2026	Gilead Sciences	Arcellx	7.50	7.80	$5.00	Net sales
18	March 2026	Biogen	Apellis Pharmaceuticals	5.60	6.10	$4.00	Net sales ×2
19	March 2026	Eli Lilly	Centessa Pharmaceuticals	6.30	7.80	Up to $9.00	Reg. approval ×3

Terms are taken from the form of CVR agreement filed as an exhibit to the merger, arrangement or scheme documents; no executed CVR agreement is publicly filed for any deal in the library. Amryt and Gracell CVR values shown per ADS. Eli Lilly / atai–Beckley (announced July 16, 2026; up to $2.50 per CVR) falls outside the H1 2026 survey window and is excluded from all Part I statistics.

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Contingent Value Rights

A Drafting Guide for Biopharma M&A