

# ‘Silent Killer’ Acquisitions in Pharma: A Comparative Analysis of *ex ante* Control over Innovation-Suppressive Deals in the U.S. and the European Union

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## Abstract

This article investigates the regulatory blind spots that allow ‘killer’ acquisitions in the pharmaceutical sector to escape merger control in both the United States and the European Union. Such acquisitions, where incumbents acquire nascent rivals to discontinue competing drug development, pose a systemic threat to innovation, particularly when transactions are structured to evade *ex ante* antitrust review. Applying a comparative legal assessment, this paper identifies shared structural deficiencies: threshold-based jurisdictional triggers, narrow definitions of control, evidentiary barriers in assessing innovation harm, and the absence of instruments to monitor sub-threshold pipeline transactions. It highlights how, despite doctrinal recognition of potential competition and innovation markets, enforcement remains impeded by statutory constructs and procedural *lacunae*. Drawing on empirical studies and recent institutional developments, the article proposes a suite of targeted reforms. These include a central registry targeted to sub-threshold pharmaceutical transactions involving overlapping pipelines, a clinical pipeline continuity obligation, expansion of the U.S. “commercially significant rights” test, and a redefinition of control under the EUMR. It further advocates for an EU-wide call-in system for innovation-sensitive deals. Ultimately, the article argues that recalibrating merger control to reflect the economics of pharmaceutical R&D is critical to preserving dynamic competition and safeguarding public health innovation.

Keywords: killer acquisitions, merger control, pharmaceutical innovation, *ex ante* competition law, section 7 Clayton Act, article 22 EUMR, nascent competition.

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## 1. Introduction

“The supreme art of war is to subdue the enemy without fighting.” – *Sun Tzu, The Art of War*

In the contemporary pharmaceutical industry, this ancient axiom finds a chilling parallel in the phenomenon of ‘killer’ acquisitions: transactions whereby incumbents acquire nascent rivals in order to quell their innovations

rather than develop them. As per *Cunningham, Ederer, and Ma*, in pharma, such deals allow dominant firms to preempt future competition by acquiring and subsequently discontinuing their R&D pipelines.<sup>1</sup> Here, the ‘enemy’ is subdued not in the market arena but through the discontinuation of a clinical trial.

The strategy’s effectiveness stems from its elusiveness. These transactions are frequently engineered to evade antitrust scrutiny, falling below statutory notification thresholds or circumventing provisions that trigger *ex ante* review. The result? A regulatory *lacuna* to the detriment of public health—a price that consumers pay without ever perceiving the loss.

This gap presents a challenge to the architecture of antitrust law. The *ex ante* enforcement instruments in the world’s two largest pharmaceutical markets, namely, Section 7 of the Clayton Act in the United States and Council Regulation (EC) No. 139/2004 (hereinafter “EUMR”) in the European Union, are the primary ramparts against such transactions.<sup>2</sup> Howbeit, the very nature of these acquisitions is to bypass them.

In response, this paper conducts a comparative, policy-based analysis of these two review systems. Thus, it aims to assess the procedural and practical ability of the EUMR and Section 7 of the Clayton Act in addressing

innovation-suppressive acquisitions in the pharmaceutical sector before they occur.

### 1.1. *The Problem in Pharma*

Killer acquisitions need not take the form of a headline-grabbing merger. Many are ‘silent’ acquisitions that fly below the regulatory radar, such as buying exclusive patent rights or pipeline assets via licensing agreements, which do not formally transfer corporate control. Thereby, incumbents can eliminate budding rivals with little scrutiny.

Empirical evidence confirms that this problem is systemic. In the United States between 1989 and 2010, an estimated 5.3% to 7.4% of all pharma acquisitions were consistent with the killer acquisition profile.<sup>3</sup> Critically, when an incumbent buys a target with an overlapping pipeline, the acquired project is 39.6% less likely to continue its development relative to an equivalent project that remains independent.

Post-acquisition termination of R&D is markedly skewed toward deals that evade merger control. It was observed that suspect acquisitions disproportionately cluster just below the U.S. pre-merger notification threshold.<sup>4</sup> Tellingly, acquired drug projects just below the reporting cutoff have a 1.8% chance of reaching market, versus 9.1% for projects from just-above-threshold deals. The innovation fallout is significant; absent these killer acquisitions, the industry’s annual continuation rate of

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<sup>1</sup> Colleen Cunningham, Florian Ederer, and Song Ma, ‘*Killer Acquisitions*’ (2021) 129 *Journal of Political Economy* 649.

<sup>2</sup> Clayton Antitrust Act 1914 § 7 (15 USC § 18); Council Regulation (EC) 139/2004 of 20 January 2004 on the control of concentrations between undertakings (EC Merger Regulation) [2004] OJ L24/1.

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<sup>3</sup> Colleen Cunningham, Florian Ederer, and Song Ma, ‘*Killer Acquisitions*’ (2021) 129 *Journal of Political Economy* 649.

<sup>4</sup> Appendix 1.

drug R&D projects would be about 4.8% higher (or 7 additional new drugs per year).<sup>5</sup>

European markets have exhibited a parallel problem. From 2014 to 2018, 240 deals involving overlapping pipelines were identified.<sup>6</sup> Alarming, 37% of these deals were followed by an unexplained termination of the project (strong *prima facie* signal of a killer acquisition). Notably, it was revealed that this phenomenon is not limited to outright M&A. In fact, 80.9% of the suspect cases were licensing agreements, R&D projects, asset purchases, or other deals.<sup>7</sup>

The consequence? Once a drug project is discontinued post-acquisition, *ex post* enforcement is not likely to revive the foreclosed R&D.<sup>8</sup> As *Hemphill & Wu* observed, the results of diminished innovation are of grave concern, amounting to a systemic drag on future competition and a reduced range of available treatments for patients.<sup>9</sup> This is exacerbated by the fact that emerging biotechs now account for the discovery of more than ⅓ of the innovative drugs that reach the market.<sup>10</sup> Thus, there is a clear policy imperative: without strengthening *ex ante* review systems

to ‘catch’ these silent killer acquisitions, society risks a continued erosion of pharmaceutical innovation, to the peril of long-run competition and public welfare.

## 2. Diagnostic Analysis of Merger Control Frameworks

### 2.1. In the U.S.

U.S. acquisition control relies on Section 7 of the Clayton Act and the Hart–Scott–Rodino Act (1976) (hereinafter “HSR”) *ex ante* notification system.<sup>11</sup> Section 7 of the Clayton Act, 15 U.S.C. § 18, prohibits acquisitions “where the effect may be substantially to lessen competition, or to tend to create a monopoly.” In practice, enforcement is carried out through the HSR Act, which requires merging parties to notify the Federal Trade Commission (hereinafter “FTC”) and Department of Justice (hereinafter “DOJ”) of transactions above thresholds, then observe a waiting period while the agencies review the deal. Furthermore, the FTC/DOJ Merger Guidelines outline how agencies assess whether a merger may lessen competition, purportedly including consideration of potential and innovation competition.<sup>12</sup> Yet, despite this broad doctrinal canvas, the U.S. regime struggles to prevent killer acquisitions in pharma.

First, the 2025 HSR notification thresholds establish that transactions valued at \$126.4 million or less do not require any HSR filing. Such size-based cutoffs are poorly

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<sup>5</sup> Colleen Cunningham, Florian Ederer, and Song Ma, ‘Killer Acquisitions’ (2021) 129 *Journal of Political Economy* 649.

<sup>6</sup> DG Competition, ‘*Ex-post evaluation: EU competition enforcement and acquisitions of innovative competitors in the pharma sector*’ (2024).

<sup>7</sup> Appendix 2.

<sup>8</sup> DG Competition, ‘*Ex-post evaluation: EU competition enforcement and acquisitions of innovative competitors in the pharma sector*’ (2024).

<sup>9</sup> C. Scott Hemphill and Tim Wu, ‘*Nascent Competitors*’ (2020) 168 *U.Pa.L.Rev* 1879.

<sup>10</sup> DG Competition, ‘*Ex-post evaluation: EU competition enforcement and acquisitions of innovative competitors in the pharma sector*’ (2024).

<sup>11</sup> Clayton Antitrust Act § 7, 15 U.S.C. § 18;

Hart–Scott–Rodino Antitrust Improvements Act of 1976, (15 U.S.C. § 18a).

<sup>12</sup> US Department of Justice and Federal Trade Commission, Merger Guidelines (18 December 2023).

tailored to pharmaceutical innovation, where an early-stage biotech's pipeline might be acquired for less. More importantly, the problem is compounded by focusing on formal corporate acquisitions and full asset transfers. For instance, the transfer of "all commercially significant rights" to a pharmaceutical patent is treated as an asset acquisition requiring notification.<sup>13</sup> However, firms can craft licensing agreements that stop short of transferring all commercially significant rights (e.g. limiting the license to a particular indication or territory), thereby bypassing the HSR filing trigger.

Second, the evidentiary standards pose high barriers. U.S. courts have been reluctant to block mergers based on harm to innovation or potential competition unless the threat is concrete. The statutory phrase "the effect may be substantially to lessen competition" suggests a probabilistic standard, as the US Supreme Court noted.<sup>14</sup> In practice, however, lower courts often demand proof that the nascent rival would likely have grown into a significant competitor. For example, in *FTC v. Steris Corp.* (2015), the FTC alleged the killer acquisition of a firm developing a novel sterilization technology that had not yet entered the U.S. market.<sup>15</sup> Still, the court denied a preliminary injunction, finding the evidence that the target "probably would have entered" insufficient. These standards are ill-suited to early-stage pharma acquisitions, where it is inherently uncertain whether a given drug in development will ever

reach the market, or how strongly it would compete if it did. Requiring enforcers to prove such future outcomes to a court's satisfaction creates a nearly fatal evidentiary burden in many cases.

Third, traditional merger analysis frameworks are not well equipped to value innovation. Agencies have defined innovation markets or considered harm to R&D, notably in the Genzyme/Novazyme case, but such practices remain the exception.<sup>16</sup> Enforcement in pharma focuses on overlaps in existing product markets (e.g. requiring divestitures when two drug portfolios contain marketed products for the same disease). However, early-stage acquisitions often involve no current product overlap, given that the project is pre-commercial, which allows parties to argue that no current competition would be lost.

Lastly, there is no output or price effect to analyze when a pipeline project is suspected to be discontinued post-merger. Unless there is clear evidence, such as internal documents revealing an 'acquire to kill' motive, enforcers struggle to make the case that consumers will be harmed by the absence of a future drug. This is a structural flaw; the current system lacks an effective metric to evidence deals that eliminate potential competition before that competition ever manifests.

Consequently, authorities have come under pressure to sharpen their tools. This is illustrated in recent cases such as Illumina/PacBio and Illumina/Grail.<sup>17</sup> Albeit, the

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<sup>13</sup> 16 C.F.R. § 801.2(g).

<sup>14</sup> *Brown Shoe Co Inc v United States* 370 US 294, 323 (1962), noting that Section 7 deals in "probabilities, not certainties."

<sup>15</sup> *Federal Trade Commission v Steris Corporation et al.* No. 1:15-CV-1080 (N.D. Ohio 2015).

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<sup>16</sup> Genzyme/Novazyme, FTC Docket No. 021 0026 (2004).

<sup>17</sup> Illumina/PacBio, FTC Docket No. 9387 (2020); Illumina/Grail, FTC Docket No. 9401 (2024).

aforementioned involved transactions large enough to trigger review. The typical silent pharma acquisition remains elusive.

## 2.2. In the European Union

The European Union system is centered around the EUMR on the control of concentrations between undertakings. This framework establishes a ‘one-stop shop’ system whereby concentrations exceeding a €5 billion combined worldwide turnover and a minimum €250 million EU-wide turnover for each undertaking must be notified to the European Commission for approval. This ensures large cross-border mergers are reviewed at the EU level, avoiding multiple national filings.

The EUMR’s thresholds leave an enforcement gap comparable to that in the U.S. regime: transactions involving early-stage pharma innovators often fall below. The EU sought to patch this gap through Article 22 EUMR. This provision allows one or more Member States to refer a concentration to the Commission if the deal affects interstate trade and threatens competition, even when the EUMR’s turnover thresholds are not met. Historically, the European Commission discouraged Article 22 referrals where the referring Member State lacked national jurisdiction, to preserve legal certainty. In response, Member States have begun to expand referral jurisdiction at the national level. Notably, up to 16 Member States are expected to have “call-in” powers by

2025.<sup>18</sup> These powers enable authorities, *ex officio*, to refer the review of a transaction falling below notification thresholds, exercised when potential harms to protected public interests are identified. These responses may feed into the EU system, but this approach is no panacea. Enforcement still depends on national law and *ad hoc* willingness to act, and it may still miss deals lacking any local nexus.

Another fundamental obstacle lies in the definitional scope of a “concentration” under Article 3 of the EUMR. Per Article 3(1), a concentration arises where there is a “change of control on a lasting basis”. “Control” is defined in Article 3(2) as the possibility of exercising “decisive influence” over another undertaking’s strategic decisions. While this definition is adequate for classic mergers and full acquisitions, killer acquisitions are frequently structured to not amount to the acquisition of control. For instance, early-stage firms can license out pipeline assets without ceding *de jure* control, and acquirers may obtain exclusivity over only a subset of rights (such as commercialization in the EU or for a particular disease) while leaving R&D or manufacturing with the target.<sup>19</sup>

But even aside from jurisdictional questions, the substantive challenges echo those in the U.S. framework. In theory, the Commission can examine whether a pharmaceutical acquisition eliminates a potential rival

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<sup>18</sup> O. Guersent, ‘EU actively encouraging Member States to adopt call-in powers, Guersent says’ *Global Competition Review* (6 March 2024).

<sup>19</sup> Björn Lundqvist, “Killer Acquisitions and Other Forms of Anticompetitive Collaborations: Part I” (2021) BRICS Competition Law and Policy Series WP22/2021/01.

product that ‘but for’ the merger might have matured into a competitive threat. Indeed, the Commission has, in the past, evaluated overlaps in R&D pipelines and required divestments to protect future competition. For example, in Dow/DuPont, it treated reduced innovation competition as a key theory of harm.<sup>20</sup> *Lear* confirms that in the few large pharma deals that were reviewed, the Commission appropriately analyzed killer acquisition scenarios.<sup>21</sup> Yet, when the target’s product is still years from market, the counterfactual conditional that the target would have independently brought a successful drug to market can be contested, and counterparties still argue that no competition is lost if pipelines are pre-commercial.

Lastly, just as in the U.S., EU authorities face an evidentiary quandary. The lack of immediate price/output effects makes it hard to quantify harm. Extensive non-public data is often needed to discern a killer’s motive, and even then outcomes are uncertain, as many projects fail for legitimate reasons.<sup>22</sup> Thus, many early-stage pharma acquisitions bypass enforcement on substantive grounds.

### 3. Policy Recommendation

#### 3.1. Diagnostic Summary of the Flaws

As the analysis has shown, both merger control frameworks share structural limitations. First, a threshold-driven jurisdiction, based on transaction value

(U.S. HSR Act) or turnover (EU EUMR), excludes many acquisitions of early-stage projects whose commercial footprint is minimal. Second, control-based definitions of notifiable transactions miss transactions that fall short of formal control but still extinguish competitive threats. Third, substantive evaluation gaps persist, where enforcement tends to focus on overlaps in existing product markets, rather than dynamic pipeline competition. Fourth, evidentiary limitations, such as the difficulty of proving future harm to innovation, fatally raise the bar for agencies. Fifth, there is a lack of innovation review tools to systematically assess R&D foreclosure. Finally, the information invisibility of sub-threshold deals prevents early detection. Together, these factors maintain a continuously exploited regulatory *lacuna*.

#### 3.2. General Recommendations

Effective adjustment must start with solutions that are jurisdiction-neutral and capable of improving merger control across both frameworks.

First, establish a mandatory, pharma-specific Central Registry for Pipeline Transactions to log all pharmaceutical transactions involving any overlapping pipeline asset, irrespective of transaction value or formal change in corporate control.<sup>23</sup> In the U.S., this registry would be administered by the FTC, and in Europe, by DG Competition via a joint DG COMP–EMA platform leveraging the European Medicines Agency’s expertise in

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<sup>20</sup> Dow/DuPont (Case M.7932) Commission Decision C(2017) 1946 final [2017] OJ C 353.

<sup>21</sup> DG Competition, ‘*Ex-post evaluation: EU competition enforcement and acquisitions of innovative competitors in the pharma sector*’ (2024).

<sup>22</sup> *ibid.*

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<sup>23</sup> DG Competition, ‘*Ex-post evaluation: EU competition enforcement and acquisitions of innovative competitors in the pharma sector*’ (2024), 286. This proposal is inspired by the registry or “notice,” system discussed in the report.

drug development. Registration would not automatically trigger a review but would give agencies a period of time to file any inquiries that could later be reviewed (in the EU upon referral). This directly addresses the current transparency gap caused by lack of public information on pipeline deals, generating visibility surrounding sub-threshold acquisitions potentially available for review.

Second, implement a Clinical Pipeline Continuity Obligation. For any flagged acquisition inquired through the Central Registry for Pipeline Transactions, parties should be required to submit a Pipeline Continuity Plan to enforcement authorities. The plan would detail the status of each overlapping drug project, the combined firm's development intentions for those projects, the scientific rationale for any change in development priority, and expected timelines. About 18 to 24 months post-merger, the authority would conduct follow-ups to review the actual development status against the plan. The goal is to create institutional memory and accountability so agencies can later assess whether a merged firm unjustifiably terminated a pipeline that was ostensibly viable. This mechanism addresses the evidentiary limitations suffered by enforcers in court, providing contemporaneous evidence to substantiate claims on innovation harm. This oversight does not mandate continuation of R&D, as firms remain free to discontinue projects for legitimate reasons, but it introduces transparency deterrence.

### 3.2.1. U.S. Recommendations

In the U.S., merger policy should be recalibrated to capture transactions that confer functional control over

pharmaceutical innovation assets, even if they fall outside current formal criteria. As seen, per HSR, an exclusive patent license is only reportable if it transfers "all commercially significant rights" to the licensee. Statutory reform should close this gap by codifying a substance-over-form approach. Any exclusive or quasi-exclusive license that gives the acquirer control over a product's development or commercialization trajectory would be deemed an asset acquisition for HSR purposes, even if nominal IP ownership is not fully transferred. This would ensure that incumbent firms cannot bypass merger review by using partial exclusivity agreements to accomplish what is essentially an acquisition of a pipeline competitor.

### 3.2.2. European Union Recommendations

In the EU, merger policy should expand the legal definition of "control" under Article 3 EUMR in the context of pharmaceutical assets. The EUMR deems a concentration to arise only when an acquirer gains the ability to exercise decisive influence over an entire undertaking. Because this can leave certain transactions outside EUMR scope, a narrow reform could authorize the Commission to treat such exclusive licenses as concentrations if they effectively transfer the project's 'destiny' to the licensee. In other words, if Party A grants Party B an exclusive right to develop and commercialize a drug for a particular indication or region, the EU's reformed law would permit viewing Party B as acquiring a controlling interest in an enterprise consisting of that pipeline asset. This would allow enforcers to review

transactions that stop short of full acquisitions yet pose similar competitive risks.

Importantly, EU regulators should institute an EU-harmonized “call-in” system for below-threshold mergers in high-innovation sectors. As seen, several Member States have or are planning to enact national “call-in” powers to refer small but significant deals to authorities. However, not all Member States have such tools. The EU should therefore enact a directive requiring each Member State to empower its authority to flag and refer mergers that fall below national thresholds but meet defined risk criteria, such as the acquisition of a firm whose R&D pipeline constitutes a sufficiently probable future competitive constraint on the acquirer. These criteria should be consistent across the EU to prevent *forum* shopping and provide legal certainty. Such a reform would feed into the existing Article 22 EUMR process and diminish its dependence on happenstance intervention while integrating the protection of innovation into its merger control regime.

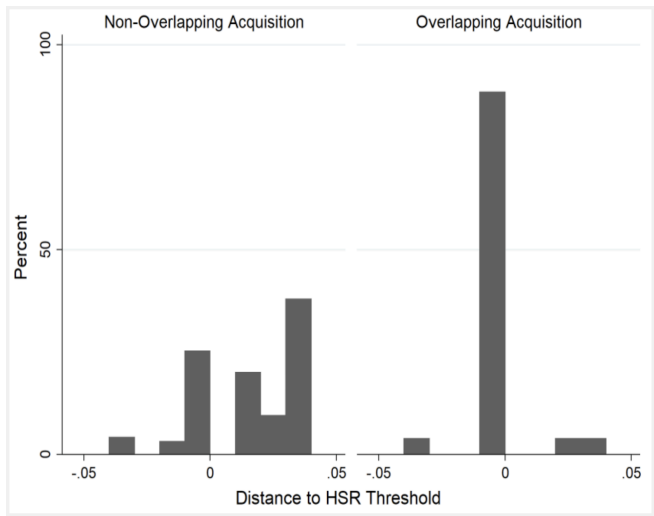
#### 4. Conclusion

Addressing the pervasiveness of silent killer acquisitions demands more than fragmented reform. It requires a cohesive recalibration of merger control that involves statutory, procedural, and evidentiary reform in tune with the structure of innovation markets. The prevailing logic remains, as Mark Zuckerberg once said, “better to buy than to compete”. That mentality will persist so long as acquisition remains the cheaper, less risky path. Therefore, reform must reorient this economic calculus. Neutralizing

nascent competition must become more costly than contending in the market. Only by aligning legal deterrence with the true value of foregone innovation can the system guard against the unseen losses of tomorrow’s breakthroughs. Each project terminated post-acquisition represents not just a lost opportunity, but a therapy that might have changed, prolonged, or even saved a life.

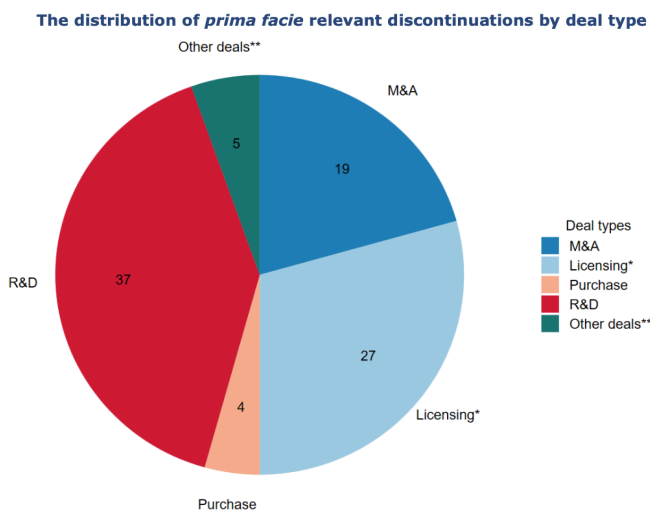
## Appendices

### Appendix 1:



Colleen Cunningham, Florian Ederer, and Song Ma, 'Killer Acquisitions' (2021) 129 *Journal of Political Economy* 649, Figure 5, 46.

### Appendix 2:



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