Intellectual property rights and value-based pricing

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Abstract

Patents let pharmaceutical firms price new therapeutics largely free from competitive constraint. Outside the U.S., value-based pricing (VBP) ties market access and price to evidence of therapeutic benefit or cost-effectiveness after regulatory approval. This chapter examines what VBP does to pharmaceutical market value: how much the owner can capture, which R&D directions get funded, and whether an unfavorable decision destroys or merely delays value realization. We compare structurally different VBP models: Germany's added health benefit system and England's cost-effectiveness threshold. We test their effect on market value using stock market reactions to reimbursement decisions for publicly listed firms, 2000–2025. Neither favorable nor unfavorable VBP decisions move stock prices in either country: investors do not treat them as new information about firm value. The null result implies how little VBP threatens the incentive to innovate, and how firms and policymakers should weigh reimbursement risk against patent-driven return expectations.

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I. Introduction

Pharmaceutical patents exist to allow prices above marginal cost. In many markets outside the United States, however, value-based pricing (VBP) intervenes as a third institutional layer between the patent grant, regulatory approval and the price actually paid: a gatekeeper that decides how much of that legal right to price converts into revenue.

VBP denotes payer schemes that condition a new drug's price or reimbursement on an assessment of the therapeutic value it adds over existing care, rather than on development cost. In practice, VBP schemes take at least two structurally different forms. First, comparative added benefit pricing schemes perform a categorical added health benefit test that feeds into negotiated pricing, as in Germany's assessments under the *Act to Reorganize the Pharmaceuticals Market* (AMNOG).[1] Second, cost-effectiveness threshold pricing schemes apply a continuous cost-effectiveness threshold that functions as an implicit price ceiling, as in England's technology appraisals by the National Institute for Health and Care Excellence (NICE). Both filter the same underlying patent right, through different mechanisms and with different consequences for what gets rewarded.[2]

Prior literature largely treats intellectual property protection and value-based pricing as separate policy domains. One strand is concerned with patent scope, duration and appropriability[3], the other deals with payer design and cost-effectiveness methodology.[4] This chapter connects the two: we ask what VBP does to the market value of pharmaceutical IP once granted, and use financial markets, which price firms on expected future profit, as an empirical instrument for that question.

We proceed in three steps. First, we set out the three stages at which a drug's IP is valued: patent grant, regulatory approval, and VBP. We identify two channels through which VBP acts on that value: how much of a therapy's social value the innovator can appropriate and which direction R&D investment is steered toward. We consider whether an unfavorable decision reduces market value or merely delays its realization. Second, we test these channels empirically, using an event-study design to ask whether the publication of German added health benefit ratings and English NICE recommendations moves the stock prices of the firms holding the

[1] Gesetz Zur Neuordnung Des Arzneimittelmarktes in Der Gesetzlichen Krankenversicherung, Bundesgesetzblatt I Nr. 67 2262 (2011), http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl110s2262.pdf.
[2] NICE, *National Institute for Health and Care Excellence Technology Appraisal and Highly Specialised Technologies Guidance: The Manual*, NICE process and methods https://www.nice.org.uk/process/pmg36/ (2022), https://www.nice.org.uk/process/pmg36/resources/nice-technology-appraisal-and-highly-specialised-technologies-guidance-the-manual-pdf-72286779244741.
[3] Eric Budish et al., "Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials," *American Economic Review* 105, no. 7 (2015): 2044–85, https://doi.org/10.1257/aer.20131176.
[4] Helen Dakin et al., "The Influence of Cost-Effectiveness and Other Factors on Nice Decisions," *Health Economics* 24, no. 10 (2015): 1256–71, https://doi.org/10.1002/hec.3086.

relevant IP. Third, we complement this market-based evidence with data on drug availability and launch timing, asking whether VBP's effect on market value also shows up in whether and when drugs reach patients.

For practitioners managing IP strategy in biopharmaceutical markets, the question this raises is whether VBP decisions are priced in the market value. Do investors already treat VBP outcomes as a predictable cost of doing business? Do VBP decisions remain as a source of unpriced risk to the value of a patent portfolio?

II. VBP and the Value of Biopharmaceutical Intellectual Property

A drug's intellectual property is valued at three successive stages of the pharmaceutical life cycle: patent protection, regulatory approval, and VBP. At each stage different information is demanded, and failure at any stage reduces the value the underlying IP can generate. Our concern is the third stage.

The initial decision of an inventor to file for patent protection ensures that inventors can claim legal rights of their biomedical technology, the production process of a drug and certain mechanisms of action. Patent protection makes the drug's information appropriable to the firm for 20 years in the U.S. and Europe. At this stage, firms invest substantial resources to move to the second stage of regulatory approval as the assets created here will only generate value if market access is successful. Estimates of the median capitalized Research and Development (R&D) cost per product for drugs and biologic agents approved by the U.S. Food and Drug Administration (FDA) range at $1.1 billion, including failed trials.[5] The market value is mostly private information and driven by the expectations whether investments in R&D for a therapeutic target will generate future economic value. Failure to show therapeutic effects means that ongoing or subsequent clinical trials to demonstrate safety and efficacy are discontinued and 60% of all R&D costs can be attributed to attrition.[6] If the initial investigation fails, the drug's market value is then bound to whether any adjustments in the invention may address different therapeutic targets and thus, the project cycle of a different medical therapy.

The second stage is the regulatory approval process which ensures that new drugs can be considered safe and effective to be marketed and thus turn the IP of the drug's patent portfolio into a commercialized product to offer new treatment pathways for patients suffering from a

[5] Olivier J. Wouters et al., "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018," *JAMA* 323, no. 9 (2020): 844–53, https://doi.org/10.1001/jama.2020.1166.
[6] Kathy Fernando et al., "Achieving End-to-End Success in the Clinic: Pfizer's Learnings on R&D Productivity," *Drug Discovery Today* 27, no. 3 (2022): 697–704, https://doi.org/10.1016/j.drudis.2021.12.010.

certain disease. To obtain approval, firms need to ensure that the new medical entity meets the quality standards which is ultimately shown in phase III clinical trials. While rejection rates after Phase III are as low as 5-10% depending on regulatory approval body, they determine market access such that firms will not be able to recoup the sunk R&D investments if this stage fails.[7] When regulatory agencies take diverging decisions, the risk of a subsequent marketing withdrawal increases. In all cases, this means that the market value of the initial invention largely drops, although it may still be valuable to inform development of subsequent products and R&D.

VBP is the third stage which is the entry door to many public health insurance schemes across European countries, Canada, Australia and beyond. VBP introduces a system-level check to ask whether the new drug is effective or cost-effective relative to existing therapeutic alternatives against current therapy standards, to negotiate prices based on information about the product's value, or both. The information that is demanded includes information about both costs and effects in a given health care setting, demanding pieces of evidence that goes beyond published clinical trial information that concentrates on efficacy and safety. One reason why health systems have introduced VBP is the presence of universal health insurance which makes individuals less price sensitive and demand less elastic.[8] Another reason was to ensure equal access to health technology including drugs by providing centralized and evidence-based guidance.[9] Under fixed health care budgets, when pharmaceutical expenditure is in competition with other service types like surgeries or medical technology, health care systems aim to align prices paid for a new drug to the individual and social value gained within a certain coverage scheme. Industry endorses VBP over cost-based pricing, conditional on a broad definition of value and no additional price controls.[10] When such aligned prices are considered too low by firms, they may not enter a health system. Or, VBP may lead to lower than expected prices paid if the added health benefit is not rewarded by the health care system. A negative VBP based reimbursement decision then reduces market value either by shrinking the accessible market (exit) or by compressing the achievable margin (lower price).

[7] Simon Dalla Torre Di Sanguinetto et al., "A Comparative Review of Marketing Authorization Decisions in Switzerland, the EU, and the USA," *Therapeutic Innovation & Regulatory Science* 53, no. 1 (2019): 86–94, https://doi.org/10.1177/2168479018764660.
[8] Margaret K. Kyle, "Lessons for the United States from Pharmaceutical Regulation Abroad," *Journal of Economic Perspectives* 39, no. 2 (2025): 53–78, https://doi.org/10.1257/jep.20241418.
[9] Guidelines International Network, *Patient Involvement in HTA*, 2026, https://g-i-n.net/toolkit/the-hta-context.
[10] EFPIA, *A Value-Based Approach to Pricing*, EFPIA position paper (European Federation of Pharmaceutical Industries and Associations, 2023), https://www.efpia.eu/media/677284/a-value-based-approach-to-pricing-2.pdf.

III. Models of VBP and their Logic

VBP systems act as a system-level filter between regulatory approval and reimbursement, determining what a therapy's intellectual property is worth in a given market. The United States, Germany and England occupy three distinct positions on this dimension from no binding value assessment to a categorical added benefit test to a continuous cost-effectiveness threshold. Table 1 summarizes how each determines market access, price, the type of innovation rewarded and modifiers of VBP decisions.

Our point of reference is the United States where after the FDA's marketing authorization approval, manufacturers have large degrees of freedom when setting their prices: the government funded Medicare scheme for individuals above the age of 65 already mandates manufacturer rebates tied to a statutory "best price", and the 340B program of the Public Health Service Act requires discounts for eligible providers. However, all mechanisms operate as mandated rebates, leaving the manufacturer's launch price itself unexamined for value. Drug coverage is not universal such that drugs are sold at widely different prices to different buyers, with Pharmacy Benefits Manager (PBM) schemes and health insurances negotiating prices and defining drug formularies.[11] Given the market size, the substantial R&D investments made and mostly unrestricted price setting at marketing authorization of new drugs, makes the U.S. the reference point against which VBP-imposed price corrections can be measured.

Information on the value provided by pharmaceuticals exists in the U.S., but whether it shapes prices is opaque. The Institute for Clinical and Economic Review (ICER institute) regularly publishes drug level cost-effectiveness evidence. A study by ICER institute staff estimates that pricing 73 drugs to a $100k–150k/quality adjusted life year (QALY) threshold would cut spending by 11-37%.[12] Separately, manufacturers exchange clinical and economic information with health plans, PBMs and pricing committees through the Academy of Managed Care Pharmacy (AMCP) dossier standard.[13] But AMCP dossiers are not public, and ICER institute assessments carry no coverage mandate, so it remains largely unclear whether either ties price to value.

[11] Kyle, "Lessons for the United States from Pharmaceutical Regulation Abroad."
[12] Kai Yeung et al., "Value-Based Pricing of US Prescription Drugs: Estimated Savings Using Reports From the Institute for Clinical and Economic Review," *JAMA Health Forum* 3, no. 12 (2022): e224631, https://doi.org/10.1001/jamahealthforum.2022.4631.
[13] AMCP, "AMCP Format for Formulary Submissions 5.0 - Guidance on Submission of Pre-Approval and Post-Approval Clinical and Economic Information Evidence," *JMCP* 30, no. Number 4-b (2024), https://www.amcp.org/sites/default/files/2024-04/AMCP-Format-5.0-JMCP-web_0.pdf.

Given that the prices in the U.S. are exceeding foreign prices by far, the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169)[14] and the Most Favored Nation (MFN) Pricing Executive Order 14297 of 2025 (with an earlier version planned in 2020)[15], introduce internal and external reference pricing schemes to curb prices paid by the public Medicare and Medicaid insurance targeting the roughly 30% of U.S. pharmaceutical sales accounted for by Medicare.[16] IRA targets selected high-volume single source drugs and uses a negotiation-based discount scheme referencing the years a drug is on the market and discount ceilings as benchmark for price cuts. To align prices paid in the U.S. to other countries, the MFN pricing scheme uses external reference pricing to use the lowest price paid in a basket of countries of the Organization for Economic Co-operation and Development (OECD) to determine the price paid by U.S. Medicare and Medicaid in selected single-source drugs. While the IRA's internal reference pricing scheme explicitly rules out cost-effectiveness as a criterion, MFN offers a plausible channel through which foreign VBP decisions could indirectly reach U.S. prices: governments included in the reference basket set prices directly through VBP, so a price shaped by VBP decisions abroad could become the qualifying "most favored" benchmark. Whether this channel is empirically material remains an open question.

At approval stage, the FDA's expedited pathways grant concessions on speed that are loosely linked to value judgments.[17] Priority review compresses the review clock and breakthrough designation intensifies agency guidance. In the case of accelerated approval, the FDA allows surrogate endpoints to substitute for clinical outcomes. The market may read these designations as a signal of higher expected value, but they embody no assessment of comparative or cost-effectiveness value that could inform pricing; their effect is to bring products to market faster, not to price them. U.S. prices and drug availability are thus largely detached from value assessment at present, with foreign VBP logic entering only prospectively and indirectly through MFN.

Germany and England, by contrast, make value assessment the explicit condition of market access and price determination: Germany through added benefit ratings that feed into price negotiations. England through a cost-effectiveness threshold that indirectly caps prices.

[14] Centers for Medicare & Medicaid Services, *Fact Sheet: Medicare Drug Price Negotiation Program Revised Guidance* (2023), https://www.cms.gov/files/document/fact-sheetrevised-drug-price-negotiation-program-guidance-june-2023.pdf.
[15] Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," Executive Order, May 12, 2025, https://www.govinfo.gov/content/pkg/DCPD-202500591/pdf/DCPD-202500591.pdf.
[16] Kate Ho and Ariel Pakes, "Policy Options for the Drug Pricing Conundrum," *Proceedings of the National Academy of Sciences* 122, no. 9 (2025): e2418540122, https://doi.org/10.1073/pnas.2418540122.
[17] Center for Drug Evaluation and Research, "Expedited Programs for Serious Conditions | Drugs and Biologics," FDA, December 14, 2023, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics.

Germany introduced appraisals of the added health benefit in six categories (major / considerable / minor / non-quantifiable[18] / none / less) compared to the standard of care in 2011.[19] The goal is to ensure access to drugs while containing pharmaceutical expenditure within the German statutory health insurance that covers 90% of the German population. After approval by the EMA and within three months after German market entry, manufacturers must submit a health technology assessment (HTA). Manufacturers may set prices freely with the negotiated price applying from month seven (month 13 until 2022) after market entry. The HTA is comprehensive and covers information about the affected patient population size, the appropriate comparative therapy and evidence about health benefit in four dimensions: mortality, morbidity, quality of life and adverse events. The strength of the submitted evidence is assessed with evidence supported by randomized clinical trials receiving a higher weight. The Institute of Quality and Efficiency in Health Care (IQWIG), an HTA agency regularly commissioned for assessment assesses the submitted dossier. After a stakeholder commenting phase, the German Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA), the legal institution of the self-administered German statutory health insurance system, makes the final rating. Benefit assessments are made not at the level of the drug as a whole but separately for each patient group defined within the approved indication, so that a single product may receive a considerable added benefit for one subgroup and none for another; the negotiated price then reflects a blended outcome across these ratings, weighted by the size of the patient groups concerned. The manufacturer and the umbrella organization of statutory health insurances (GKV Spitzenverband) then use the overall health benefit rating in confidential price negotiations to negotiate a reimbursed price that reflects a price premium for the new therapy on the current comparator therapy. Additional guard rails were specified in 2022 that clarified limited price premiums for drugs with non-quantifiable added benefit and a 10% rebate of drugs with no added benefit when the comparator is still under patent protection.

Evaluations of the AMNOG process on the impact on drug prices have focused on oncology treatments. The reform led to lower prices of 15.8% with no strategic reactions by manufacturers to accommodate price levels[20] and a stronger alignment of prices with the value shown.[21]

[18] This means that the evidence suggests a positive benefit, but the evidence base is not meeting standards or is too uncertain.
[19] Gesetz Zur Neuordnung Des Arzneimittelmarktes in Der Gesetzlichen Krankenversicherung.
[20] Giovanni Righetti, "The Impact of Health Technology Assessment on Pharmaceutical Prices: Evidence from Germany," *The European Journal of Health Economics*, ahead of print, April 25, 2026, https://doi.org/10.1007/s10198-026-01924-5.
[21] Victoria D. Lauenroth et al., "Lessons From The Impact Of Price Regulation On The Pricing Of Anticancer Drugs In Germany," *Health Affairs* 39, no. 7 (2020): 1185–93, https://doi.org/10.1377/hlthaff.2019.01122.

While rationales from the price negotiations are not transparent, the price premium paid is aligned with the rating of health benefit, with higher ratings allowing higher price premiums.[22]

The risk of AMNOG to drug manufacturers rests in the outcome of the benefit assessment stage, which may result in a "no added health benefit" designation at the drug level. The expected annual costs of the treatment are reported in the dossier and a cost-efficiency analysis is a theoretical last resort if there is no agreement between manufacturer and health insurers. As such, the value assessment concentrates on therapeutic benefit compared to existing standards. By 2025, 38% of the 409 substances never received a positive added benefit.[23] In that case, the price of the new drug is then aligned with the price of the comparator therapy which may include generic drug options that are off-patent so that a patented product carrying full development costs is reimbursed at the level of an off-patent generic. Because of the AMNOG process and subsequent price determination, firms have decided to completely withdraw from the German market since drugs without a positive assessment were more than ten times more likely to exit (25% vs 2%).[24]

In two therapeutic areas, where particular incentives for development are socially desirable, AMNOG is more lenient in judging the benefit of the drug. First, for orphan drugs, no price negotiation takes place if the annual turnover is below €30 million annually. Second, for designated reserve antibiotics, positive added health benefit is automatically assigned.

[22] Victoria Desirée Lauenroth and Tom Stargardt, "Pharmaceutical Pricing in Germany: How Is Value Determined within the Scope of AMNOG?," *Value in Health* 20 (2017): 927–35, https://doi.org/10.1016/j.jval.2017.04.006.
[23] IGES Institut, "Anwendungsgebiete," Arzneimittel-Atlas, January 7, 2026, https://www.arzneimittel-atlas.de/nutzenbewertung/amnog-reporting/neubewertung/index_html.
[24] Ariel D. Stern et al., "The Impact Of Price Regulation On The Availability Of New Drugs In Germany," *Health Affairs* 38, no. 7 (2019): 1182–87, https://doi.org/10.1377/hlthaff.2018.05142.

Table 1: VBP Logics in the United States, Germany and England

VBP Logic / Dimension	Unregulated launch pricing (U.S.)	Comparative added benefit pricing (Germany)	Cost-effectiveness threshold pricing (England)
Mechanism	No binding national value assessment. Prices set by manufacturers, negotiated privately by PBMs and insurers. For Medicare/Medicaid only: IRA introduces internal reference pricing (QALYs and cost-effectiveness explicitly excluded); MFN introduces external reference pricing.	Manufacturer submits benefit dossier at market entry. IQWiG reviews; G-BA appraises added benefit against a defined comparator, assigning one of six categorical levels.	NICE cost-utility analysis: incremental costs and QALYs combined into an ICER, assessed at or near approval; single HTA manual across programmes since 2022
Price determination	Manufacturer set, constrained by payer negotiation power and PBM formulary negotiation, IRA sets price as discount by years since launch, MFN uses lowest foreign price	Free launch price for six months; added benefit rating caps subsequent reimbursement-price negotiation between manufacturer and GKV-SV. Failing agreement, an arbitration board sets the price.	Threshold nominally £20,000–30,000/QALY as NHS opportunity cost; price typically lowered via confidential patient access scheme discounts to bring the ICER within range
What innovation is rewarded	No central value signal; prices need not reflect socially desired investment. FDA expedited pathways steer at approval stage	Patient-relevant added benefit in (preferably randomized) trials against the comparator; convenience or safety gains count only when captured in clinical endpoints.	Measurable QALY gains at acceptable cost; benefits held equal in value except for disease severity
Risks for innovators	Limited domestic pricing risk; emerging statutory risk from IRA negotiation and MFN	"No added benefit" rating triggers severe price compression; some drugs withdrawn	Rejection or restriction where cost per QALY is too high
Rare diseases	Orphan exclusivity and tax credits beyond patent rights; IRA excludes certain orphan drugs	Presumed added benefit up to €30m annual sales	Highly Specialised Technologies programme for ultra-rare conditions; evidential uncertainty accepted
Value modifiers	-	Classified reserve antibiotics receive presumed added benefit	Disease severity modifier (replaced end-of-life); separate access route for oncology drugs with uncertain evidence (Cancer Drugs Fund)

Notes: Authors' own compilation based on sources discussed in the main text. AMNOG: Act to Reorganize the Pharmaceuticals Market; FDA: Food and Drug Administration; G-BA: Gemeinsamer Bundesausschuss (Federal Joint Committee); GKV-SV: GKV-Spitzenverband (statutory health insurance umbrella organization); HTA: health technology assessment; ICER: incremental cost-effectiveness ratio; IQWiG: Institute for Quality and Efficiency in Health Care; IRA: Inflation Reduction Act; MFN: Most Favored Nation pricing; NICE: National Institute for Health and Care Excellence; NHS: National Health Service; PBM: Pharmacy Benefit Manager; QALY: quality-adjusted life year.

In contrast to Germany, the decisions made by the English National Institute for Health and Care Excellence (NICE) do not ask whether a drug is therapeutically better, but whether the

health gain is worth the cost. The central health-related outcome considered is the QALY and the reimbursement decision is based on the incremental cost-effectiveness (ICER) threshold, which reflects the opportunity cost to the English National Health Service (NHS) of the drug displaced.[25] NICE appraisals for drugs are aimed to be commissioned shortly after marketing approval. Since 2000, the technology appraisal committee recommended 85% of the 1,085 drug and non-drug treatments assessed for reimbursement of which 650 were recommended unconditionally and 435 only recommend reimbursement for some patient groups the drug is approved for.[26] About 15% of recommendations were for the drug not to be used or only in research (30 of 201 not recommended). Because the threshold binds on cost-effectiveness rather than price directly, manufacturers commonly secure a positive recommendation by offering a confidential discount through a patient access scheme, lowering the effective price until the drug's ICER falls within the acceptable range.[27]

Given that the English NHS is operating under a fixed budget, there is a deliberate threshold of £20–30k above which a recommendation to cover the drug becomes increasingly unlikely. When NICE appraisals began in 2000, the £20–30k threshold was not stated but inferred from observed decisions. Empirical studies suggest that the stated threshold predicts 80% of decisions, but that the implied threshold is well above the stated one as the rejection probability at £40,000/QALY is 50%, for example.[28] A recent industry report suggests that this threshold has been shifting downwards over time, coming closer to the implicitly stated £20–30k threshold.[29] The threshold range has been raised to £25–35k amid trade negotiations with the U.S. government over pharmaceutical pricing and investment.[30] This shift is attributed in press coverage to political rather than health-opportunity-cost considerations.[31]

As such, the NICE decision-making process rewards innovation that provides gains in measurable QALYs at acceptable cost levels to the English NHS. Receiving a "not recommended" designation at drug or patient group level poses a risk to manufacturers as national access through the English NHS is then excluded. The NICE appraisal program further implies that

[25] Laura Vallejo-Torres et al., "Politicised Changes to the NICE Threshold Risk Making Cost-Effectiveness Analysis Performative, Not Informative," *Applied Health Economics and Health Policy* 24, no. 2 (2026): 243–46, https://doi.org/10.1007/s40258-025-01026-y.
[26] NICE, "Technology Appraisal Data: Appraisal Recommendations," The National Institute for Health and Care Excellence, NICE, July 7, 2026, https://www.nice.org.uk/what-nice-does/our-guidance/about-technology-appraisal-guidance/technology-appraisal-data-appraisal-recommendations.
[27] "Patient Access Schemes and Pricing Agreements," NICE Website: The National Institute for Health and Care Excellence, NICE, accessed July 27, 2026, https://www.nice.org.uk/what-nice-does/patient-access-schemes-and-pricing-agreements.
[28] Dakin et al., "The Influence of Cost-Effectiveness and Other Factors on Nice Decisions."
[29] Kurt Taylor et al., *NICE Decision-Making ICER Threshold Analysis* (Petauri Evidence (formerly Delta Hat), 2025), https://www.abpi.org.uk/media/x3md0bwu/delta-hat_nice-icer-threshold-report-may-2025.pdf.
[30] Vallejo-Torres et al., "Politicised Changes to the NICE Threshold Risk Making Cost-Effectiveness Analysis Performative, Not Informative."
[31] Joanna Robertson, "NICE Cost-Effectiveness Thresholds Increased as UK Strikes Trade Deal with United States," *The Pharmaceutical Journal*, December 2, 2025, https://pharmaceutical-journal.com/article/news/nice-cost-effectiveness-thresholds-increased-as-uk-strikes-trade-deal-with-united-states.

value is considered equally independent from the type of drug, with a tiered disease severity modifier in exceptional circumstances. Since the update of NICE's methods manual where end-of-life was a stated modifier, higher thresholds of £36k to £50k are acceptable for disease severity when there are proportional and absolute QALY shortfalls for a disease to allow a within-threshold value adjustment.[32] Other modifiers like magnitude of the benefit, curative potential, rarity or whether the drug constitutes an innovation to an unmet need were rejected and are not particularly rewarded.

For oncology drugs, the Cancer Drugs Fund introduced by NHS England constitutes a special access route to cancer treatments with uncertain evidence, with a similar expansion to innovative drugs besides cancer in 2022. This means that NICE can recommend a cancer drug for routine commissioning while additional evidence is collected until the evidence is reassessed. As such this access scheme is an institutional response to appraise cancer drugs close to approval. Of all cancer approvals made by the European Medicines Agency (EMA) between 2009 and 2013 for which NICE published appraisals, survival gains were shown for 35% of indications and quality of life improvements in 10%, with the benefit still uncertain in about half of indications after a median of 5.4 years.[33]

IV. Pharmaceutical Market Value under VBP

Having set out the stages at which market value is determined, we examine how VBP reshapes that value. VBP explicitly or implicitly determines prices and acts as a selection filter. In doing so it affects how much of a therapy's social value the innovator can appropriate and the direction in which R&D investment is steered. We take each in turn and discuss empirical evidence from Germany and England to analyze how VBP impacts the appropriation and direction of market value.

Patent portfolios that comprise the information to produce and market a new medical therapy carry knowledge that could not be marketed under perfect competition without patent protection.[34] With patent protection and the related elements of regulatory approval, the information embedded in a drug's patent portfolio turns into a marketable commodity that allows firms to bear the risk of R&D costs by acting as a monopolist and receiving marketing exclusivity for 10–15 years after marketing approval. To take the relatively high risks of uncertainty in medical

[32] Aris Angelis et al., "The Evolving Nature of Health Technology Assessment: A Critical Appraisal of NICE's New Methods Manual," *Value in Health* 26, no. 10 (2023): 1503–9, https://doi.org/10.1016/j.jval.2023.05.015.
[33] Rumona Dickson et al., "EMA and NICE Appraisal Processes for Cancer Drugs: Current Status and Uncertainties," *Applied Health Economics and Health Policy* 16, no. 4 (2018): 429–32, https://doi.org/10.1007/s40258-018-0393-7.
[34] Kenneth J. Arrow, "Economic Welfare and the Allocation of Resources for Invention," in *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton University Press, 1962).

R&D, large pharmaceutical corporations insure against the risk of failure of a single project within the portfolio of projects pursued.

VBP systems add another modifier to the expected value of IP. While the expected return on a patent in markets without VBP is based on the expected sales in this market, the expected returns in markets with VBP are conditional on VBP factors such as performance against the standard of care and other incentives and restrictions in the VBP regulations.

Looking at how much of the social value of a drug can be appropriated empirically in VBP schemes in Germany and England, we see that value is aligned with prices and that manufacturers receive a substantial share of the value provided to the health system. However, no cross-country comparison exists that benchmarks different VBP schemes in terms of appropriation. The existing evidence is constrained by small samples of drugs evaluated such that no portfolio-wide appropriation estimate exists. Studies for Germany have analyzed the alignment of the price premium to the added health benefit rating to consider the realized price. A study of the early phase of AMNOG appraisals 2011-2016 revealed that any added health benefit rating raised the price premium over the comparator therapy by about 227% relative to a no added health benefit rating, higher mark-ups realized with the extent of benefit and mortality gains commanding the largest markup.[35] Other drivers were the share of patient population appraised as benefiting from the drug, European price levels and whether the comparator is a generic. Under AMNOG, the innovator appropriates the share of value as an increasing function of added benefit, with a hard floor at zero premium when no added benefit is proven. The new guard rails providing additional criteria for price premia paid depending on added benefit introduced in 2022 and confidential net prices are likely to lower price premia over the comparator and make indirect appropriation via price premia more difficult. Since there is only a single blended price determined after benefit assessment and price negotiation, appropriation per se is not a clean function of demonstrated value, but a population-weighted average. As such, prices cannot track value when it is heterogeneous within subgroups.[36]

For the English NICE appraisals, existing evidence examines how the value provided is shared between patients (the health system) and manufacturers, taking into consideration the health opportunity cost as the value forgone elsewhere when using the new drug across the total lifetime.[37] Considering a threshold of £15,000/QALY as opportunity cost and based on data

[35] Lauenroth and Stargardt, "Pharmaceutical Pricing in Germany."
[36] Katrin Kleining et al., "Ten Years of German Benefit Assessment: Price Analysis for Drugs with Unproven Additional Benefit," *Health Economics, Policy and Law* 19, no. 2 (2024): 216–33, https://doi.org/10.1017/S1744133123000117.
[37] Beth Woods et al., "Estimating the Shares of the Value of Branded Pharmaceuticals Accruing to Manufacturers and to Patients Served by Health Systems," *Health Economics* 30, no. 11 (2021): 2649–66, https://doi.org/10.1002/hec.4393; Beth Woods et al., "Achieving Dynamic

from 12 NICE appraisals concentrating on higher ICERs, end-of-life and biologic cases, the study identifies that 51% of potential net health gains are accrued by the health system and the other 49% by manufacturers, with a large spread across the study sample. For the same set of drugs, the study group additionally analyzed the static versus dynamic efficiency trade-off and estimated an optimal share of about 20% (range 6-51% when excluding quality effects) provided to manufacturers to maximize long-term population health, given how innovation responds to payment.[38] Based on the assumption that £15,000/QALY reflects the true opportunity cost, the current share of roughly 50% is well above the estimated optimum of 20%, suggesting that the NHS could secure the same or greater long-term population health gains by reducing the manufacturer's share toward that optimum, rather than that the current arrangement produces a net loss to the NHS. The approval norm here depends on the innovation elasticity, opportunity cost of health, and the proportion of value generated during the patent period and not the consumption value of health.

Beyond defining what level of innovation is valued and can be appropriated by manufacturers, VBP systems also shape which technologies a health care system takes up. Apart from funding basic research such as technological platforms or in emergencies where population health is affected at scale, as during the COVID-19 pandemic, governments support the R&D of individual medical therapies only indirectly.[39] It is almost exclusively up to the biopharmaceutical industry to decide which health problems and diseases to address first. If no direction is set for what type of technological progress is valued, equilibrium incentives steer inventors toward higher mark-up products and larger markets.[40,41] The innovation that is then targeted may not be optimal from a social value point of view. For example, preventive technologies which may have greater social benefits as they deliver long-term health outcomes may be targeted less than high-tech procedures that may reach fewer individuals and smaller health effects. For the U.S., several studies suggest that the 2006 Medicare Part D expansion making the prescription drug market larger and more profitable, firms respond by developing more drugs, but not necessarily drugs that are more scientifically novel.[42] The evidence suggests that firms respond and change direction of innovation, but mostly by developing less risky drugs.

Efficiency in Pharmaceutical Innovation: Identifying the Optimal Share of Value and Payments Required," *Health Economics* 33, no. 4 (2024): 804–19, https://doi.org/10.1002/hec.4795.

[38] Woods et al., "Achieving Dynamic Efficiency in Pharmaceutical Innovation."

[39] Bhaven N. Sampat and Frank R. Lichtenberg, "What Are The Respective Roles Of The Public And Private Sectors In Pharmaceutical Innovation?," *Health Affairs* 30, no. 2 (2011): 332–39, https://doi.org/10.1377/hlthaff.2009.0917.

[40] Daron Acemoglu and Joshua Linn, "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry," *The Quarterly Journal of Economics* 119, no. 3 (2004): 1049–90.

[41] Daron Acemoglu, "Distorted Innovation: Does the Market Get the Direction of Technology Right?," *AEA Papers and Proceedings* 113 (2023): 1–28.

[42] David Dranove et al., "Does Consumer Demand Pull Scientifically Novel Drug Innovation?," *The RAND Journal of Economics* 53, no. 3 (2022): 590–638, https://doi.org/10.1111/1756-2171.12422.

VBP systems add extra dimensions to the decision on which drug development programs firms should pursue by making expected revenue dependent on the social value the innovations provide against the current standard of care. However, since strict VBP would make development in certain areas unattractive, health care systems have added exceptions from these valuations. One common exception is orphan drugs where the number of trial participants is usually lower than what VBP agencies usually require and in addition valuation methods like QALYs may understate disease burden.[43] The other common exception is cancer drugs, where high prices are accepted even though the evidence base might not yet be exhaustive. The cost-per-QALY approach used by the English NICE would, applied strictly, reject many oncology drugs, since these often deliver modest survival gains at high cost. In response, the Cancer Drugs Fund, established in its current form in 2016, provides a dedicated budget that secures earlier access to new cancer therapies with "plausible potential" while evidence on their effectiveness is collected.[44,45]

VBP reimbursement rules and its exemptions shape when and where products are launched. The Patients W.A.I.T. Indicator, published by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and produced by IQVIA, illustrates both dimensions.[46] Of the oncology drugs approved in Europe between 2021 and 2024, Germany had 51 of 56 (91%) available, compared with 33 of 56 (59%) in England. For orphan drugs, Germany had 64 of 66 (97%) available, against 33 of 66 (50%) in England.

Two patterns emerge from these data. The first is a between-country difference in overall stringency: across both segments, availability in Germany is far higher than in England. This pattern is consistent with the two systems applying value thresholds of differing severity, though administrative capacity, negotiation timelines, and firms' own launch-sequencing decisions could also contribute to the same aggregate gap and cannot be ruled out from these data alone. The German added benefit logic admits a broad range of products at a negotiated price, whereas the English cost-per-QALY threshold more frequently withholds reimbursement where the incremental cost per health gain is judged too high. The second, and for the present argument more telling, is a within-country difference between therapeutic areas. In England, oncology availability (59%) exceeds orphan availability (50%), whereas in Germany the ordering is

[43] Sandra Nestler-Parr et al., "Challenges in Research and Health Technology Assessment of Rare Disease Technologies: Report of the ISPOR Rare Disease Special Interest Group," *Value in Health* 21, no. 5 (2018): 493–500, https://doi.org/10.1016/j.jval.2018.03.004.
[44] NHS England, *NHS England » Cancer Drugs Fund*, 2026, https://www.england.nhs.uk/cancer/cdf/.
[45] Dickson et al., "EMA and NICE Appraisal Processes for Cancer Drugs."
[46] Max Newton et al., *EFPIA Patients W.A.I.T. Indicator 2025 Survey* (IQVIA, 2026).

reversed, with orphan (97%) marginally ahead of oncology (91%). The two systems do not merely differ in how much they admit; they differ in which segments they favor relative to one another.

For Germany and England, there is no causal empirical evidence that shows how the direction of innovation has been influenced after VBP schemes were introduced. Although both countries are considerable markets in absolute terms, they are relatively small from a global perspective: Germany accounted for approximately 4.6% and the United Kingdom for approximately 2.8% of the $1,528.5 billion world pharmaceutical market in 2024.[47] Considering availability of drugs launched internationally and time to access in international comparison is suggestive of how VBP is changing the direction of innovation received in particular market. The median time difference in availability between Germany and the United States is 4 months and Germany had fewer drugs available compared to the United States (80% vs 92% of 599 drugs approved between 2004 and 2018).[48]

Considering the drugs that were not available in either market, in Germany, twice as many drugs are not available compared to the United States. However, from the drugs missed in Germany, therapeutic area composition was similar. An exception were orphan drugs where 48% compared to 18% were disproportionally marketed in the United States. Comparing availability and launch times with other European markets and as an effect of the introduction of AMNOG, while overall delays in launch time were decreasing, Germany had a 4-month average delay in market launch after the introduction of AMNOG while availability rates for Germany of drugs launched internationally increased by roughly 6%.[49]

VBP also interacts with the dynamics of competitive displacement. Absent any value assessment, the entry of a superior therapy drives down the prices and market shares of older products, so that value is destroyed mainly where it falls on therapies already becoming obsolete — typically branded products losing ground to generics.[50] VBP changes this by acting as a selection filter, and the competitor being displaced need not be a generic: it may be another branded

[47] Authors own calculation based on: EFPIA, *The Pharmaceutical Industry in Figures – Key Data 2025*, EFPIA (European Federation of Pharmaceutical Industries and Associations, 2025), https://www.efpia.eu/media/uj0popel/the-pharmaceutical-industry-in-figures-2025.pdf; IQVIA, *Top 10 Pharmaceutical Markets Worldwide, 2024* (2025), https://www.iqvia.com/-/media/iqvia/pdfs/canada/2024-trends/english/top10worldwidesales_24.pdf.
[48] Katharina Blankart et al., "Availability of New Medicines in the US and Germany From 2004 to 2018," *JAMA Network Open* 5, no. 8 (2022): e2229231, https://doi.org/10.1001/jamanetworkopen.2022.29231.
[49] Melanie Büssgen and Tom Stargardt, "Does Health Technology Assessment Compromise Access to Pharmaceuticals?," *The European Journal of Health Economics* 24, no. 3 (2023): 437–51, https://doi.org/10.1007/s10198-022-01484-4.
[50] Frank R. Lichtenberg, "Are Drug Prices Subject to Creative Destruction? Evidence from the US, 1997–2017," *Health Economics* 30, no. 8 (2021): 1910–32, https://doi.org/10.1002/hec.4283.

therapy, or even a non-pharmaceutical intervention. When the new therapy is genuinely superior, VBP identifies and rewards it, accelerating displacement of the incumbent.

Evidence from the German market illustrates this withholding channel.[51] Physician adoption of a new drug responds to the publication of its AMNOG quality rating rather than to the drug's underlying quality, net of observable drug and physician characteristics, consistent with a negative rating slowing diffusion independent of whether the drug remains clinically usable. Its market value is unrealized through reduced uptake. Since added health benefit ratings are not randomly assigned, this cannot rule out that unobserved factors correlated with both the rating and physician behavior contribute to the pattern. Direct evidence on the other half of the distinction, especially whether patented incumbents are displaced by superior VBP-selected entrants, remains absent, and we treat it as an open question. The broader implication is that VBP operates as a signal about where and when market value is realized, not merely whether it exists, which is information that may be relevant to financial markets.

V. Stock market reactions as Valuation Indicators

For pharmaceutical firms with free trading stocks, stock market reactions to news in the successive stages of the pharmaceutical life cycle can be interpreted as a signal for the adjustment of the expected value of the underlying IP. A share price reflects the firm's expected future profits. This profit depends on the number of pharmaceutical inventions that end up being available to patients and generating revenue. News from different stages of the life cycle provides an update to the market on the probability of market entry and ultimately whether the IP can be used to generate profits.

Previous studies have analyzed stock market reactions for the announcement of trial results and FDA approval decisions. Regarding trial results, in particular for phase III clinical trials, when biopharmaceutical firms announce successful trial results, stock prices typically experience positive abnormal returns on the announcement date. Early positive trial results announced before a trial's planned completion (often due to strong efficacy or safety interim findings) generate substantial positive abnormal returns due to their unexpected nature. In contrast, trials that successfully meet their primary endpoints at full maturity generate much milder positive abnormal returns and there is a general upward trend in the firm's valuations even before such positive news are announced. In contrast, negative clinical trial announcements (such as failing to meet primary endpoints, a lack of efficacy, or premature suspension due to safety and adverse

[51] Katharina Blankart and Tom Stargardt, "The Impact of Drug Quality Ratings from Health Technology Assessments on the Adoption of New Drugs by Physicians in Germany," *Health Economics* 29, no. S1 (2020): 63–82, https://doi.org/10.1002/hec.4108.

events) inflict severe and immediate negative abnormal returns that persist longer than positive gains. However, a firm's drug portfolio size acts as a key buffer against clinical setbacks. Firms with only up to five drug products are extremely vulnerable to negative trial results, whereas highly diversified firms (more than 45 products) experience only small stock price fluctuations following a negative clinical announcement.[52]

Because clinical trial results are already public by the time the FDA issues an approval, positive regulatory decisions are largely anticipated by the market and rarely trigger massive, unexpected price spikes for standard drugs. However, negative regulatory outcomes result in substantial shareholder wealth destruction that far exceeds the impact of positive approvals.[53]

This literature shows that markets react more strongly to unexpected signals at the beginning pharmaceutical life cycle, both for clinical trial results and for FDA approval decisions. This pattern reflects expectations about the value of IP as it advances through this cycle from the more uncertain clinical trials phase up to the more predictable regulatory decisions. VBP decisions are then a further step after regulatory approval that provide signals on the expected revenues from a pharmaceutical and hence the value of the IP.

VI. Empirical Analysis: Stock Market Responses to VBP Decisions

In the following, we use stock market returns to estimate the effect of a VBP decision on market value. While the existing literature has focused on stock market responses to clinical trial results and FDA approvals, reactions to VBP decisions have not yet been studied. Stock market reactions to VBP decisions are a joint proxy for the market's expectation about the VBP decision and the impact these decisions have on expected profits of the firm. We use a market model to account for prior movements in firms' stock prices and to distinguish whether abnormal returns after the VBP decision differed significantly from the baseline estimated with data from the

[52] Thomas J. Hwang, "Stock Market Returns and Clinical Trial Results of Investigational Compounds: An Event Study Analysis of Large Biopharmaceutical Companies," *PLOS ONE* 8, no. 8 (2013): e71966, https://doi.org/10.1371/journal.pone.0071966; Manish Singh et al., "The Reaction of Sponsor Stock Prices to Clinical Trial Outcomes: An Event Study Analysis," *PLoS ONE* 17, no. 9 (2022): e0272851, https://doi.org/10.1371/journal.pone.0272851; Jeffrey M. Rothenstein et al., "Company Stock Prices Before and After Public Announcements Related to Oncology Drugs," *JNCI: Journal of the National Cancer Institute* 103, no. 20 (2011): 1507–12, https://doi.org/10.1093/jnci/djr338; Semen Budennyy et al., "New Drugs and Stock Market: A Machine Learning Framework for Predicting Pharma Market Reaction to Clinical Trial Announcements," *Scientific Reports* 13, no. 1 (2023): 12817, https://doi.org/10.1038/s41598-023-39301-4.

[53] Jorge V. Pérez-Rodríguez and Beatriz G. L. Valcarcel, "Do Product Innovation and News about the R&D Process Produce Large Price Changes and Overreaction? The Case of Pharmaceutical Stock Prices," *Applied Economics* 44, no. 17 (2012): 2217–29, https://doi.org/10.1080/00036846.2011.562172; Silvijus Abramavičius et al., "Stock Price Reaction to the Drug Development Setbacks in the Pharmaceutical Industry," *DARU Journal of Pharmaceutical Sciences* 29, no. 1 (2021): 1–11, https://doi.org/10.1007/s40199-020-00349-6; Anurag Sharma and Nelson Lacey, "Linking Product Development Outcomes to Market Valuation of the Firm: The Case of the U.S. Pharmaceutical Industry*," *Journal of Product Innovation Management* 21, no. 5 (2004): 297–308, https://doi.org/10.1111/j.0737-6782.2004.00084.x.

previous year. Details about data sources and the empirical strategy used are provided in the Appendix.

Table 2 reports the composition of the analytic sample underlying the event study: the number of drugs and firms covered under each VBP system, the number of drugs from firms with a single drug in the decision data, and the distribution of decision outcomes. The apparent gap between AMNOG's 38.2% positive rate and NICE's 82.1% is not directly comparable. The NICE figure pools unconditional and optimized recommendations compared to exclusions from the NHS funding when not recommended. AMNOG ratings are issued per patient group, and a resolution that rates one patient group as having an added benefit and another as having none enters both outcome groups (53 of the 266 German resolutions in our sample; 14 of the 527 English firm–date events). The shares in the table are therefore shares of outcome-group events, not of resolutions.

Table 2: VBP Decisions in Germany and England

	G-BA decisions (2011-2025)	**NICE decisions (2000-2025)**
Drugs	262	526
Firms	59	107
Drugs from single portfolio firms	16	64
% positive (added health benefit / recommended)	38.2	82.1
% neutral / negative (no added health benefit / not recommended)	61.8	17.9
% Cancer Drugs Fund	—	6.8

Figures 1 and 2 show stock market reactions following value-based pricing decisions in Germany (Figure 1) and England (Figure 2). As an outcome, we show the mean abnormal return across events on each trading day before and after the value-based pricing decision, separated by whether the decision was favorable or not. The ten trading days before the announcement serve as a test of anticipation effects. Pre- and post-period coefficients are based on a market model calibration that accounts for how the stock performed against the market in the year before the event. Both countries exhibit null results: pre-periods and post-periods show no economically or statistically significant effects of the VBP decision on the stock market valuation as we do not detect any positive or negative abnormal returns. Assuming that market valuation is indicative of the downstream market value means that the VBP decision is not reflected in a measurable change to market value of the product under consideration.

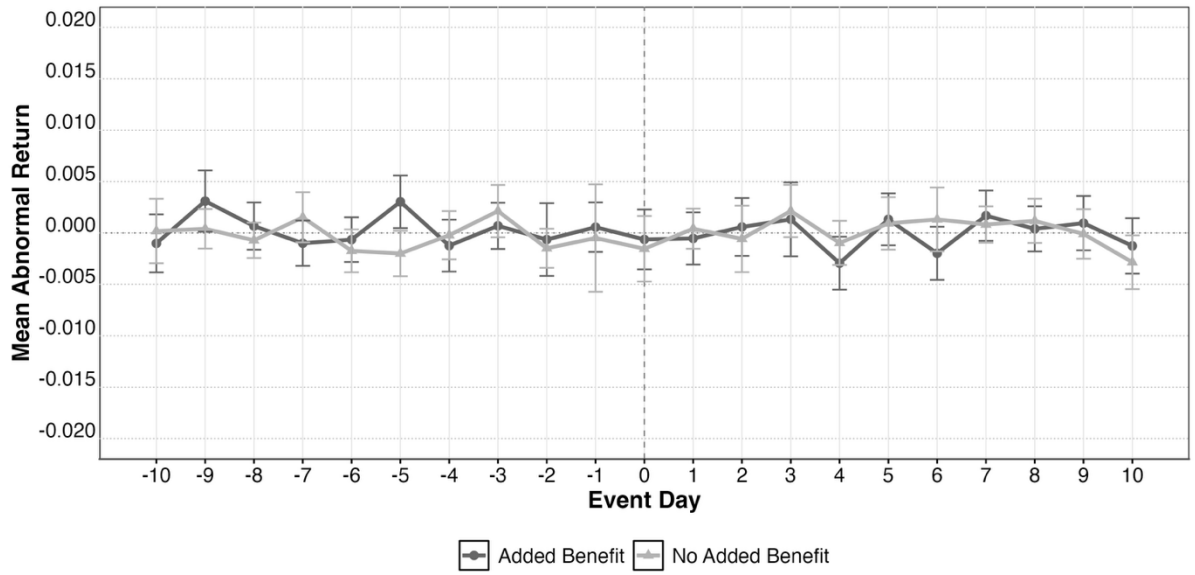


Figure 1: Abnormal stock market returns around value-based pricing decisions in Germany (G-BA added benefit ratings, 2012–2025)

We further examine heterogeneity in abnormal returns after VBP decisions by firm portfolio size, on the assumption that firms with fewer products are more reliant on the valuation of any single drug and therefore less able to absorb a VBP decision's impact within a broader portfolio. We continue to find no significant abnormal returns for both small and large portfolios in either Germany or England. Point estimates are similar in magnitude across portfolio sizes.

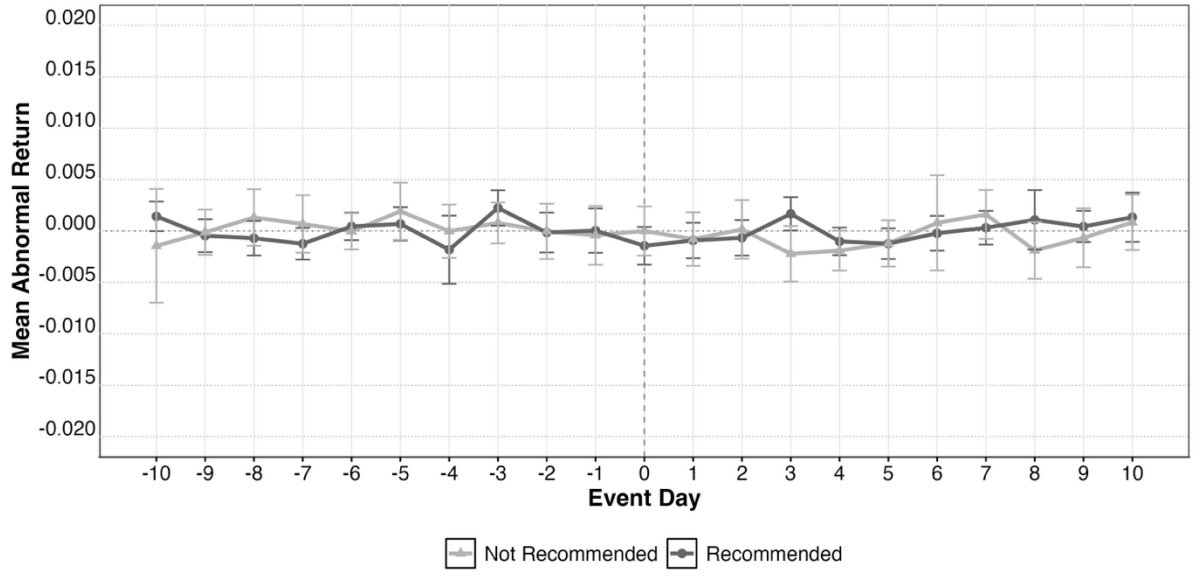


Figure 2: Abnormal stock market returns around value-based pricing decisions in England (NICE technology appraisals, 2000–2025)

VII. What the Signal Tells Us about VBP System Design

After trial results and regulatory approval, VBP decisions are the last information that signals the value of pharmaceutical IP. While previous studies have documented that markets react to news about trial results and regulatory approval, we find no stock market reactions to VBP decisions. Against the backdrop that also for trial results and regulatory approval decisions reactions from stock markets were stronger for unexpected news, the null-result for stock market reactions to VBP decisions can be seen as evidence for the transparency of VBP processes. Indeed, the German AMNOG and the English NICE processes rely primarily on data already known to informed market participants, even when some of it remains formally confidential, at the time of starting the process.

Transparent VBP procedures can shape innovation since firms can build expectations on the value of their IP as they also do with respect to regulatory approvals. While the dynamic efficiency of VBP schemes is still discussed in the literature[54], understanding how R&D activities are shaped by VBP incentives therefore matters. While current VBP systems include exceptions that allow for high monetary incentives in the development of pharmaceuticals in specific target areas such as pediatrics, orphan drugs or cancer drugs, the R&D incentives could also be guided by developing specific VBP schemes targeted to these groups.

VBP decisions have spillover effects on other systems that use reference prices to VBP systems, although VBP is only explicitly used in a small number of health care systems. The indirect effect of VBP decisions on pricing in other countries implies that the importance of these decisions for the firms and the respective strategic decisions go beyond the initial target market. Therefore, the absence of market reactions to VBP decisions cannot be driven by the low impact these decisions have on expected profits. Since VBP schemes assign benefits transparently, the design of the schemes can affect preferences of firms towards market entry. Social preferences on which type of innovation to reward shape which novel drugs are available in countries with VBP schemes but also shape which type of novel drugs are available in countries that refer to the VBP outcome in their reference pricing.

To represent population preferences more fairly outside the main VBP countries, VBP needs to be applied in more countries. While not all countries will be able or willing to afford a thorough system like the German AMNOG or the English NICE, there can be intermediate steps

[54] Louis P. Garrison et al., "Value-Based Pricing for Patent-Protected Medicines Over the Product Life Cycle: Pricing Anomalies in the 'Age of Cures' and Their Implications for Dynamic Efficiency," *Value in Health* 26, no. 3 (2023): 336–43, https://doi.org/10.1016/j.jval.2022.09.010.

for example, within a unified European scheme.[55] Revenues from Europe, however, are only a fraction of total revenue for globally active pharmaceutical firms. Since global VBP is neither practical nor desirable, adopting independent value assessments elsewhere could provide important guidance for future R&D development. Because U.S. policy is currently pursuing implicit reference pricing through MFN pricing, it will instead increase the importance of the existing schemes.

VIII. Conclusion

This chapter asked what value-based pricing does to the value of pharmaceutical intellectual property once a drug has cleared regulatory approval, distinguishing two channels: how much of a therapy's value the innovator can appropriate and which direction R&D investment is steered toward. To test whether these effects are visible to financial markets, we estimated abnormal returns compared to stock market indices around German added health benefit ratings and English NICE recommendations, finding no significant reaction in either country or at either end of the portfolio-size distribution.

We read this null result as evidence of transparency rather than irrelevance. Both AMNOG and NICE decisions are built on clinical and regulatory information that is already known to informed market participants by the time a formal decision is announced, so the decision itself adds little the market did not already expect. This null result does not mean VBP leaves market value untouched: German added health benefit ratings scale price premiums substantially compared to a no-benefit rating, and English NICE decisions currently leave manufacturers with a share of value well above the 20% consistent with maximizing long-term population health. VBP reallocates value and shapes where and how fast drugs reach patients; it just does so predictably enough that none of this arrives as news at the moment of decision. For IP strategy, the reassurance is qualified: transparency that keeps a domestic VBP decision from surprising investors also makes it exportable, since foreign VBP-set prices can enter reference-pricing baskets used elsewhere, including prospectively in the U.S. Our event study results speak to the immediate, visible reaction of publicly listed firms and cannot distinguish temporary volatility from permanent value effects or attribute patient welfare.

The transparency in VBP decisions can be leveraged to strengthen innovation incentives while keeping health care costs low. Contrary to cost-based approaches, value can be defined, assessed and priced by the regulator transparently without the need for additional data only

[55] Pierre Dubois, "Pharmaceutical Regulation and Incentives for Innovation in an International Perspective," *TSE Working Paper*, no. 1674 (2025).

observable to firms. Current VBP approaches do, however, rely on retrospective assessment of benefits. In the future, more weight can be put on real-world benefit assessment under pay for performance contracts that allow adjusting the value-based price to the realized benefits in the patient population.

Appendix: Estimating stock market returns from Value-Based Pricing Decisions in England and Germany

This appendix documents how we constructed the event-study dataset and the empirical strategy used to estimate stock market reactions to VBP decisions in England and Germany. We describe the three data sources (G-BA resolutions, NICE appraisals, and daily stock data), the linking procedure, and the market-model specification used to isolate abnormal returns.

a. Germany and England VBP decision data

For Germany, our dataset comprises all G-BA resolutions published between December 2011 and September 2025. As a data source, we use the published xml dataset that includes all G-BA resolutions. We include the G-BA's initial resolutions in the analysis, as these represent the first public assessment of a drug's added clinical benefit following market entry.

The G-BA assigns one of several possible benefit assessment categories as the final outcome of the VBP decision that informs subsequent price negotiations. To obtain a categorization of added vs. non added benefit that may inform stock market valuation, we use the categories "minor", "considerable", "major", and "considered proven" as signals that the drug provides an added benefit compared with the comparison therapy. We exclude decisions with a "non-quantifiable benefit" rating (56 resolutions with stock data) from the analysis. In these cases the G-BA concludes that an added benefit exists but cannot be classified into the given categories based on the available evidence, often asking for a subsequent assessment, so the rating carries no clear positive or negative signal about the drug's value. We assign the categories "considered not proven," "less benefit," and "not proven" to indicate that no added benefit has been shown. Ratings are issued per patient group within a resolution. A resolution whose patient groups receive different ratings is included in both outcome groups with the same stock price series; as a robustness check, we drop these resolutions, but results remain unaffected. When a firm receives several resolutions on the same G-BA meeting date, these are collapsed into one event for that firm and date, since the stock price reaction cannot be attributed to a single drug.

Our England dataset comprises NICE technology appraisals of pharmaceuticals published between May 2000 and August 2025 based on a publicly available file that includes all technology appraisals and the published reports of the single appraisals.[56] Mirroring the German sample, we keep for each drug only the appraisals published in the year of its first appraisal;

[56] Single technology appraisals are available from https://www.nice.org.uk/what-nice-does/our-guidance/about-technology-appraisal-guidance, last accessed August 21, 2026. The technology appraisal database was downloaded from https://www.nice.org.uk/what-nice-does/our-guidance/about-technology-appraisal-guidance/technology-appraisal-data-appraisal-recommendations, last accessed August 21, 2026.

later appraisals of the same drug for additional indications are not included. Appraisals of medical devices, procedures and other non-pharmaceutical technologies are excluded.

NICE classifies the recommendation in different categories. We focus on recommended (routine) and not-recommended decisions. We consider optimized recommendations that consider the drug cost-effective but restrict use to specific patient subgroups, particular dosing regimens, or use alongside companion diagnostics to improve cost-effectiveness; we classify these as recommended. In a robustness check, we exclude those optimized decisions.

We categorize cancer treatments by whether these were made as Cancer Drugs Fund (CDF) recommendation, considering that higher uncertainty about (cost-)effectiveness is accepted and drugs may provisionally receive coverage to collect further evidence. We excluded managed access recommendations (for non-cancer treatments) or recommendations made for "only in research". In addition, the data set includes cases in which the appraisal process was terminated for various reasons. We restrict the sample to drugs that received either a recommendation or a not recommended decision. An appraisal that recommends the drug for some patient groups and not for others contributes to both groups (14 firm–date events). The event unit is the firm–decision date: 39 appraisals involve two listed firms and enter once per firm, and 28 firm–dates combine two appraisals published on the same day, since the stock price reaction cannot be attributed to a single appraisal.

b. Stock Data / Returns

Using the firm name, we retrieve the firm's stock ticker on the exchange where it is listed. We excluded 113 appraisal rows (103 drugs) in England and 91 firm-date events (30 with and 61 without added benefit) in Germany without a public listing, or for which we could not identify a matching ticker. A further 22 German events (8 added benefit, 14 no added benefit) and 55 English events (44 recommended, 11 not recommended) were dropped because no price data could be retrieved or fewer than 100 estimation-window observations were available. For each ticker, we retrieve the corresponding national stock market index, for example S&P 500 in the U.S. for Pfizer (stock market ticker: ^GSPC). The national stock market index serves as benchmark against which abnormal returns are calculated.

We obtained daily stock prices and corresponding market index data from Yahoo Finance using the quantmod package (version 0.4.29)[57], downloaded July 28, 2026 in R. For each event,

[57] Jeffrey A. Ryan and Joshua M. Ulrich, "Quantmod: Quantitative Financial Modelling Framework," August 2, 2007, 0.4.29, https://doi.org/10.32614/CRAN.package.quantmod.

we collected data from the year before and 15 calendar days after the decision date. Daily returns are computed from prices and index levels using the quantmod Delt() function, rendering the stock and index series unitless and scale-independent. The abnormal return for each day is defined as the stock return minus the return predicted by the firm's estimated relationship with its market index.

c. Empirical Strategy

We employ a market model event study framework to isolate the abnormal stock price movement attributable to VBP decisions in England and Germany from confounding factors.[58] Building on existing estimation techniques[59], we use an estimation window of one year of trading days from day 252 to day 11 prior to the VBP decision date. We separate this period from the event window by a buffer period (days 10 to 1 prior to the decision) to prevent anticipation effects or information leakage from contaminating the normal-return benchmark. First, we estimate a firm-specific normal return model from pre-event data. Second, the approach tests whether observed returns during the event window deviate significantly from this normal benchmark. Consider Sanofi's dupilumab, which received a G-BA added health benefit rating on May 17, 2018: we take Sanofi's daily stock returns and the relevant index for its home listing (CAC 40 on Euronext Paris) from 252 to 11 trading days before the decision to estimate how Sanofi's stock normally co-moves with the French market, then ask whether its actual return on and around the decision date departs from what that relationship would predict. Formally, for each firm–drug pair, we estimate a market model via ordinary least squares[60]:

$$R_{i,t} = \alpha_i + \beta_i R_{m,t} + \epsilon_{i,t} \quad (1)$$

where $R_{i,t}$is the daily stock return, $R_{m,t}$is the daily return of the firm's home-market index, and $\alpha_i$and $\beta_i$are firm-specific parameters. Estimating β_i per firm allows each stock's sensitivity to its market to vary. Events with fewer than 100 trading-day observations in the estimation window are excluded, as parameter estimates would be unreliably precise. The abnormal return on each event day is computed as:

$$AR_{i,t} = R_{i,t} - \left(\hat{\alpha}_i + \hat{\beta}_i R_{m,t}\right) \quad (2)$$

[58] Charles J. Corrado, "Event Studies: A Methodology Review," *Accounting & Finance* 51, no. 1 (2011): 207–34, https://doi.org/10.1111/j.1467-629X.2010.00375.x.
[59] Hwang, "Stock Market Returns and Clinical Trial Results of Investigational Compounds."
[60] Laura E. Panattoni, "The Effect of Paragraph IV Decisions and Generic Entry before Patent Expiration on Brand Pharmaceutical Firms," *Journal of Health Economics* 30, no. 1 (2011): 126–45, https://doi.org/10.1016/j.jhealeco.2010.09.004.

We regress the abnormal return of each drug-firm pair on the event dummies around the event date such that we estimate:

$$AR_{i,t} = \sum_{d=-10}^{10} \gamma_d \, 1(t = d) + u_{i,t} \qquad (3)$$

where each coefficient γ_d represents the mean abnormal return on event day d, estimated across all events. Under the null hypothesis of no decision effect, all coefficients should be statistically indistinguishable from zero. If the market reacts to the VBP decision, we expect abnormal returns to depart from zero, most likely on day zero (the decision date) or in the days immediately following (1 to 10 days after the decision). The magnitude and timing of these coefficients reveal whether the market reaction is immediate and sharp. The regression provides a pre-event placebo test: day 10 to day 1 before the decision date should show no systematic abnormality if the market model is well-calibrated and if there is no information leakage before the official decision date. Standard errors are clustered at the event level.

We explore heterogeneity in market responses by a firm's portfolio size subject to VBP decisions. Diversified large-cap pharmaceutical firms with large drugs portfolios face attenuated abnormal returns because any single drug's reimbursement outcome is diluted across a large portfolio; a negative decision on one asset is less material to overall firm value than the same decision on a single-product biotech. Portfolio size is proxied by the number of distinct drugs a firm has in the full G-BA or NICE decision data before the restriction to listed firms; firms with one drug form the small-portfolio group.

We interpret abnormal returns as the market's contemporaneous assessment of decision impact, conditional on publicly available information at that time. We do not attempt to infer the "true" economic value of reimbursement decisions; such inference would require long-run data on actual clinical uptake, revenue, and competitive dynamics, and lies beyond the scope of this study. Our analysis is limited to publicly listed firms on stock markets and excludes smaller private firms and non-profit research institutions. Finally, the event study captures the immediate market reaction and cannot distinguish between permanent value destruction and temporary volatility that resolves over subsequent quarters, nor can it speak to welfare implications for patients or health systems.