

Daiichi Sankyo: prescribing integrity and access to oncology innovation

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1. Executive assessment: separate historical conduct from current access

Daiichi Sankyo is a Japan-based pharmaceutical group whose current oncology business includes antibody-drug conjugates, medicines that combine an antibody with a drug payload. Enhertu is developed and commercialized with AstraZeneca outside Japan, while Daiichi Sankyo retains exclusive Japanese rights and responsibility for manufacturing and supply under the disclosed collaboration.¹⁰ That partnership is relevant to access accountability: a product may involve multiple commercial organizations even when one company discovered the underlying technology.

The clearest historical enforcement matter selected for this report is a January 2015 U.S. civil settlement. Daiichi Sankyo Inc. agreed to pay \$39 million to resolve allegations about physician speaker programs promoting products including Azor, Benicar, Tribenzor, and Welchol. DOJ expressly stated that the claims were allegations and there had been no determination of liability.¹ The report therefore does not describe this as a conviction or as proof that every payment to a physician was improper.

Current affordability questions arise in a different setting. Enhertu's expanding indications demonstrate scientific and regulatory progress, but approval alone does not determine public reimbursement, commercial insurance coverage, or individual affordability. FDA approved additional uses in 2025 and two early-breast-cancer indications in May 2026.^{7,8} Meanwhile, NICE's published appraisal for a specified HER2-low metastatic breast-cancer setting did not recommend routine use on cost-effectiveness grounds.⁵ These decisions address different populations, jurisdictions, and evaluation questions; they are not contradictory verdicts on the medicine.

A public price reference also needs qualification. NICE's 2023 appraisal listed £1,455 per 100 mg vial, excluding VAT, based on an October 2022 price source, and disclosed a confidential NHS commercial discount.⁶ That is a historical UK list price. It is neither the disclosed NHS net price nor a U.S. patient bill, and it cannot be multiplied into a treatment-cost claim without specifying dose, duration, administration, and purchasing assumptions.

The principal conclusion is that transparency must cover both demand and financing. The historical speaker-program allegations concerned incentives behind prescribing. Today's oncology-access debate concerns the relationship between measured clinical benefit, price, resource allocation, and assistance eligibility. A strong report can examine both without suggesting that current oncology products were involved in the old settlement.

This review provides a bounded company profile with selected documented cases and access evidence. It does not rank clinical treatments, determine individual eligibility, or treat the existence of a high-cost innovative medicine as evidence of unlawful conduct.

2. Historical context and a changing corporate perimeter

DOJ's 2015 announcement described allegations involving Physician Organization and Discussion programs during 2005-2011 and other speaker programs during 2004-2011. It alleged payments for repetitive presentations, talks delivered only to a physician's own staff, and dinners exceeding the company's internal limit. The government's theory was that the remuneration induced prescriptions reimbursed by federal healthcare programs.¹ The allegations concern specified activities and periods, not a present-day census of Daiichi Sankyo's educational events.

The company released its own statement on January 9, 2015, with a Japanese parent-company cover announcement dated January 13. It confirmed an approximately \$39 million payment plus fees and costs and a corporate integrity agreement. It described cooperation with investigators and a commitment to strengthen compliance processes.² Those statements are the company's response; they do not independently establish that all reforms succeeded.

Date	Event	Why the date matters
2004-2011	Speaker-program periods in government allegations	Historical conduct scope
January 2015	U.S. civil settlement announced	Resolution, not a criminal conviction
March 2015	Ranbaxy-Sun merger completion announced	Former subsidiary boundary changes
February 2023	NICE publishes a HER2-positive appraisal	Historical price and commercial arrangement
July 2024	NICE publishes HER2-low appraisal TA992	Indication-specific reimbursement assessment
January 2025	FDA expands a metastatic-breast-cancer indication	New regulatory access pathway
May 2026	FDA approves two early-breast-cancer uses	Further expansion with distinct evidence

Ranbaxy belongs in the corporate chronology because historical pharmaceutical enforcement lists can blur ownership. Daiichi Sankyo announced completion of Ranbaxy's merger with Sun Pharma in March 2015, describing Ranbaxy as its subsidiary and the exchange of shares.⁴ This report does not treat Ranbaxy as a current Daiichi Sankyo subsidiary, and it does not transfer a Ranbaxy finding to Daiichi Sankyo Inc. simply because the businesses were historically related. Specific legal responsibility requires the record of the particular case.

The current business also cannot be understood solely through the cardiovascular products listed in the 2015 settlement. The contemporary Enhertu collaboration and regulatory announcements show a materially different oncology focus.^{8,10} That shift makes a current access assessment necessary rather than allowing the old case to stand in for the entire company.

The research-date financial-library check identified a source-version issue: Daiichi Sankyo says FY2025 financial materials originally issued in May 2026 were corrected on July 31, 2026 and superseded.³ This report does not reproduce those financial totals. Any later revenue or research-spending comparison should use the corrected version and disclose the fiscal-year convention.

3. Evidence on prescribing incentives and clinical value

The speaker-program settlement raises a specific transparency concern: compensation for education can influence demand if the event's commercial purpose overwhelms its educational substance. DOJ alleged that some Daiichi Sankyo payments covered duplicative talks or audiences consisting only of the speaker's own office staff. The settlement included a five-year corporate integrity agreement requiring internal compliance reforms.¹ A payment database can help identify relationships, but a payment entry alone cannot establish whether an event violated the law.

The appropriate unit of review would be the particular program: intended audience, actual attendance, content, frequency, compensation, and prescribing context. None of those event-level datasets was assembled for this report. The public enforcement record supports explaining the allegations and resolution, not estimating how many prescriptions were caused by the programs. The \$39 million payment is not a measured price increase or a patient-harm estimate.

For current oncology access, the principal evidence is different: clinical outcomes informing regulatory and reimbursement decisions. FDA's January 2025 Enhertu approval relied on DESTINY-Breast06, a randomized trial in 866 adults with advanced or metastatic hormone-receptor-positive disease and HER2-low or ultralow expression. Among patients with HER2-low disease, median progression-free survival was 13.2 months with Enhertu and 8.1 months with chemotherapy; the reported hazard ratio was 0.62.⁷

Those results refer to a defined study population and endpoint. Progression-free survival measures time before progression or death within the study definition. It should not be relabeled as an equal extension of overall survival, a cure rate, or an individual patient's expected result. The comparison also cannot be transferred unchanged to a different treatment line or tumor type. FDA's approval summary provides the boundary around the finding.

The May 2026 early-breast-cancer approvals were supported by separate trials. In the adjuvant study, FDA reported three-year invasive disease-free survival of 92.4% with Enhertu and 83.7% with trastuzumab emtansine. The neoadjuvant study used pathological complete response as its main endpoint, and FDA explained limitations on statistical interpretation of certain survival endpoints. The agency also noted the boxed warning for interstitial lung disease and pneumonitis.⁸

Including benefits and limitations together is necessary for a pricing report. A cost-effectiveness assessment depends on the magnitude and duration of benefit, toxicity, comparators, and the resources needed to deliver care. The existence of statistically significant benefit does not set an automatic fair price. Equally, a reimbursement disagreement does not mean the medicine has no clinical value. Those questions require connected but distinct evidence.

4. Pricing and access: an indication-specific example

NICE's TA992 recommendation provides a concrete example of the gap between licensing and funded access. Its July 2024 guidance did not recommend trastuzumab deruxtecan for specified adults with HER2-low metastatic or unresectable breast cancer after chemotherapy or qualifying early recurrence. NICE acknowledged clinical benefit but judged the most likely cost-effectiveness estimates above its acceptable range, even after considering severity and other benefits. The guidance protected existing funding arrangements for people already receiving treatment before publication.⁵

That decision concerns the stated setting. It must not be generalized into “Enhertu is banned in the UK,” “the NHS never funds Enhertu,” or “the drug failed approval.” Different biomarker groups and treatment lines can have different guidance. The relevant comparison is a specific indication under a specific appraisal, not a product name without context.

The pricing information in NICE's earlier HER2-positive appraisal is similarly precise. It gives a £1,455 list price for one 100 mg vial, excluding VAT, using an October 2022 source. It also records a commercial arrangement with a confidential NHS discount.⁶ Because the discount is not public, this review cannot calculate the actual NHS acquisition price from the list figure.

Evidence	Reported quantity	Limitation
2015 civil settlement	\$39 million, United States	Not a per-patient cost
Historical NICE price reference	£1,455 per 100 mg vial, excluding VAT	Not disclosed net procurement cost
DESTINY-Breast06 HER2-low group	Median PFS 13.2 versus 8.1 months	Not overall survival or a price
2026 adjuvant evidence	Three-year IDFS 92.4% versus 83.7%	A different population and endpoint

The clinical figures come from FDA summaries; the financial figures come from DOJ and NICE.^{1,6,7,8} They are presented together to show which inputs an access analysis needs, not to suggest they can be combined directly into a single ratio. A credible economic model would also require utilities, treatment duration, subsequent therapy, adverse-event costs, discounting, and jurisdiction-specific comparators.

Patient payment is another separate quantity. In the United States, the product website directs patients and providers to ENHERTU4U for reimbursement support and potential financial assistance, explicitly subject to eligibility and conditions and without guaranteed access or savings.⁹ The existence of that route is useful information but not a published universal out-of-pocket price.

This review makes no international price ranking. Converting the UK list figure to dollars and comparing it with a U.S. bill would mix currencies, time periods, discounts, and services. The strongest current conclusion is that clinical innovation can coexist with significant financing uncertainty, which transparent indication-specific reporting can make easier to understand.

5. Company response, current developments, and unresolved questions

Daiichi Sankyo's response to the 2015 investigation emphasized cooperation, completion of the civil agreement, and continuing improvements to policies and procedures.² DOJ's corresponding announcement explicitly characterized the settled claims as allegations without a determination of liability.¹ Those are the appropriate statements of outcome. The cited record describes a settlement, not an acquittal after trial, and it describes no criminal plea or judgment establishing a conviction.

For contemporary access, the company and AstraZeneca present Enhertu's development as a way to reach eligible patients earlier in cancer care. Their February 2026 announcement described the collaboration and an EU application milestone.¹⁰ This report uses it for the partnership structure, not to imply that an application validation was an approval. Regulatory milestones have different meanings, and later approvals can occur at different times across jurisdictions.

The fresh September 2026 review found FDA's May 15 approval of two early-stage HER2-positive breast-cancer indications and opened the agency's underlying summary.⁸ This is materially newer than the January 2025 indication often cited in older descriptions. The report includes the update while leaving individual treatment selection to clinicians; it is not a complete prescribing guide or an exhaustive list of all current Enhertu uses.

The current patient-facing financial-support page says ENHERTU4U is administered and sponsored by Daiichi Sankyo Inc. alone, despite the broader drug-development partnership. It also makes clear that reimbursement and access are not guaranteed.⁹ That detail helps identify the appropriate operational source for an access guide. It does not imply that the Foundation has tested the application process or verified an individual's benefit.

NICE's TA992 recommendation was checked directly on the guidance page during this review. The page continued to show its indication-specific nonrecommendation and original publication date.⁵ The dated guidance may be replaced or reviewed, so the research date limits this account of its status. The FDA expansion is not evidence that NICE automatically changed its position, because the jurisdictions and assessed populations differ.

The current financial library's correction notice was also checked.³ It illustrates why “latest report” is not always enough: an issuer may retain original files for reference while expressly overriding them. Any derived financial dataset must record which version was used.

These checks support a contemporary profile without implying a comprehensive audit. The review has not established the status of every lawsuit, every country reimbursement negotiation, every program application, or every historical subsidiary obligation. The report's confidence is strongest for the cited events and published terms; broader performance claims remain outside its evidence base.

6. Implications and research method

The Daiichi Sankyo record suggests a useful structure for future Pharma Foundation reporting: separate the evidence behind a prescription from the evidence behind a coverage decision. For prescribing integrity, track relationships and promotional activities without treating all industry-funded education as wrongdoing. For coverage, record the exact licensed population, the appraisal population, the comparator, the clinical endpoint, the price type, and the effective date. That structure makes disagreements visible without turning every disagreement into an accusation.

An oncology access file should distinguish at least four stages: regulatory authorization, a payer's coverage policy, operational availability at a treatment center, and the patient's financial burden. The cited FDA, NICE, and manufacturer sources each illuminate only part of that pathway.^{5,8,9} A patient may encounter obstacles at more than one stage, and a positive decision at one stage does not prove success at the others.

The next quantitative work should begin with traceable product and indication records, not a preselected conclusion about price. A model using the historical vial price would need to label its date and obtain current pricing before representing a present-day budget. Confidential discounts should remain unknown unless lawfully disclosed; they must not be estimated from unrelated markets and presented as facts. Clinical data from one trial should not be combined with costs from a different treatment setting without explicit justification.

Research for this edition used DOJ's announcement, Daiichi Sankyo's contemporaneous response, official transaction disclosures, FDA approval summaries, NICE guidance, and current company information. Primary source pages, including the NICE guidance, were read directly. Corporate materials were used for identity, partnership, program descriptions, and the company's stated position. They were not treated as independent proof of affordability outcomes.

Limitations include no confidential price access, no patient interviews, no independent economic model, no evaluation of all treatment alternatives, and no exhaustive litigation review. The 2015 settlement cannot quantify the extent of prescribing influence across the company. The clinical trials cannot establish the affordability of treatment. A publicly advertised support program cannot establish that all eligible patients receive assistance promptly. Those boundaries are substantive, because each missing dataset addresses a different claim.

This is a new research edition, not a recovered historical report or evidence of earlier Foundation achievements. Its supported findings are narrower and more useful: a resolved civil investigation into specific speaker programs; an evolving oncology business with documented clinical benefits and risks; and access decisions that depend on jurisdiction, indication, price, and eligibility. Future work can strengthen the profile by measuring those access outcomes while preserving the distinction between allegations, findings, corporate commitments, and independently observed results.

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