

TherapeuticsMD: disclosure fairness, women's health products, and the royalty transition

Research checked: 9 September 2026. Publication date: 9 September 2026. New research edition.

1. Executive assessment and the company being evaluated

TherapeuticsMD belongs in an evidence-based company review because of a specific, documented securities disclosure failure. In August 2019 the Securities and Exchange Commission issued a settled administrative order finding violations of Regulation FD and Exchange Act reporting requirements. The case concerned information about FDA discussions that the company selectively provided to securities analysts in 2017. The company agreed to a \$200,000 civil penalty and a cease-and-desist order without admitting or denying the findings.¹ This record does not support describing the company as convicted of pharmaceutical fraud, or its approved medicines as fraudulent.

The distinction between product evidence and financial communication is central. The regulator at issue was the SEC, and the failure was unequal access to material information. The information concerned an investigational women's health treatment and its prospects for FDA approval. A reader could misunderstand the case if a headline converted that connection into a finding that the FDA approved a defective medicine. This report therefore keeps regulatory approval, clinical safety, commercial access, and investor disclosure as separate questions.

Company identity also needs updating. TherapeuticsMD previously developed and commercialized women's health products. Its December 2022 transaction transferred U.S. commercialization rights and certain assets to Mayne Pharma. TherapeuticsMD continued as a pharmaceutical royalty business. Its June 2026 quarterly report describes one full-time employee and reliance on external support; it should not be presented as the same operating sales organization that existed in 2017.⁶

The central assessment is that the 2019 case demonstrates why a drug developer needs a disciplined public disclosure process during uncertain FDA negotiations. A later marketing authorization does not cure an earlier information imbalance. Conversely, an earlier disclosure violation does not answer whether a subsequently approved product is useful, affordable, or appropriate for an individual patient. Those conclusions require different evidence.

The current business raises additional questions concerning licensing, financial resilience, and disputed transaction adjustments. The latest filing describes litigation involving Mayne Pharma and substantial doubt about TherapeuticsMD's ability to continue as a going concern.⁶ These are material developments, but litigation allegations and accounting warnings are not judgments of fraud. The analysis below treats the completed SEC resolution as established history, attributes the current commercial dispute to the company's disclosures, and avoids inventing either an exoneration or an adverse verdict that the reviewed record does not contain.

2. Development history and the disclosure timeline

The SEC order places TX-004HR at the center of the 2017 events. It was one of only two candidates in TherapeuticsMD's development pipeline and the only one then under FDA review. An initial application was submitted in July 2016. FDA subsequently identified deficiencies and, in May 2017, issued a complete response letter concerning a lack of long-term safety data. TherapeuticsMD publicly disclosed the adverse development and arranged a June meeting to discuss a path forward.¹

This background helps explain materiality. For a company with a concentrated pipeline, the regulatory path for one candidate can affect expectations about financing needs, launch timing, and future revenue. Information does not have to be a final approval decision to matter. Descriptions of an agency meeting, the evidence submitted afterward, and management's assessment of that evidence can substantially change the information available to an investor.

The SEC identified two episodes. After the June 14 FDA meeting, an executive emailed analysts on June 15 and participated in follow-up communications. The public did not receive the same account. On July 17, the company released a limited public update and then supplied analysts with more detailed information about the meeting and supporting studies. The corresponding details were not disclosed through the company's public earnings call until August 3.¹

Date	Documented development	Meaning for this review
May 2017	Complete response letter disclosed	Regulatory uncertainty was public
June 2017	Private analyst communications after FDA meeting	First selective-disclosure episode
July 2017	Detailed analyst briefing after limited public update	Second episode
August 2019	SEC settled order	Civil disclosure findings and penalty
December 2022	Mayne licensing transaction closed	Operating model changed
August 2026	Latest quarterly filing reviewed	Royalty and litigation status updated

The first four entries come from the SEC order; the transaction and current entries come from subsequent company filings.^{1,6} These are event dates, not an uninterrupted account of every clinical or corporate development.

The 2018 annual report describes IMVEXXY, BIJUVA, and ANNOVERA as marketed or newly commercializing products, alongside prenatal vitamins.³ That later portfolio gives context to the business, without supplying a retrospective defense to the disclosure case. A development program can progress successfully while its sponsor still fails to communicate fairly at an earlier stage. The timeline therefore carries both outcomes: a real products business and a real, specifically bounded disclosure enforcement action.

3. What the SEC found, and what it did not decide

The most direct evidence is the nine-page administrative order, rather than a characterization of the company in a news headline. It describes emails, analyst calls, public filings, meeting minutes, and the timing of subsequent analyst research. These materials supported the SEC's conclusion that analysts received material, nonpublic information concerning the approval prospects of TX-004HR while the general investing public did not receive simultaneous or prompt equivalent disclosure.¹

An important feature of the July episode is that the company had already issued a public statement. Publication alone was insufficient because the subsequent private briefing contained additional substantive information. This illustrates an operational weakness: a company can have a public communication channel and still create unequal access when follow-up discussions go beyond it. The public statement and the analyst discussion need to be evaluated together, rather than treating the existence of an 8-K as proof that all relevant details were public.

The SEC also found that TherapeuticsMD lacked Regulation FD policies and procedures when the events occurred. The order describes later reforms, including rules requiring public disclosure, examples of potentially material information specific to the business, review protocols for external communications, and employee training. The SEC took cooperation and remedial actions into account when accepting the settlement.¹ The reforms are part of the documented resolution. Their existence is not an independent audit proving that every future communication complied.

The accompanying SEC announcement reports market movements during the episodes, including a 19.4% closing increase on June 16 and a July 17 decline that narrowed from approximately 16% in early trading to 6.6% at the close.² These observations reinforce why the information mattered to regulators. They are not a complete event study. This report has not modeled other market influences or calculated investor damages, and it does not attribute every percentage point to the private disclosures.

The legal outcome should be described precisely. The Commission made findings through a settled order; TherapeuticsMD consented without admitting or denying them. That is stronger than an untested complaint but different from a criminal conviction or a fully litigated trial judgment. The order addresses reporting obligations, not a finding that patients were deceived about the approved products or that clinical results were fabricated.

The broader analytical lesson is that commercial optimism can become material information even before a definitive regulatory event. Fair communication requires attention to the substance and timing of the message, the audience receiving it, and the information already available publicly. That inference follows from the sequence documented here; it is not a claim about undisclosed events beyond the reviewed record.

4. Access, reimbursement, and the limits of financial numbers

The reviewed sources do not establish a comparable, dated series of U.S. list prices, manufacturer net prices, and patient out-of-pocket costs for TherapeuticsMD's products. Accordingly, this report does not manufacture a price-increase chart or classify the company as a price-gouging case. The strongest access evidence is about reimbursement uncertainty and the separation between a marketing authorization and actual insurance coverage.

In its 2018 annual report, TherapeuticsMD explained that CMS had clarified that drugs approved for certain symptoms associated with menopausal vulvar and vaginal atrophy were not categorically excluded from Medicare Part D. The company also cautioned that this clarification did not guarantee coverage for IMVEXXY. It described uncertainty over coverage and cost sharing for ANNOVERA as well.³ These are the company's historical descriptions of reimbursement conditions, not this report's statement of every plan's rules in September 2026.

The distinction is useful. A product can be eligible for coverage while a particular beneficiary still encounters formulary placement, prior authorization, or cost sharing. Conversely, a high published price does not establish the amount paid by every patient. A proper access investigation would identify the product, strength, quantity, benefit design, date, geography, and assistance eligibility. It would also distinguish a prescription never filled from one filled at a negotiated or subsidized cost.

The Mayne transaction introduces another financial category. TherapeuticsMD's January 2023 completion announcement described \$140 million for the license and specified assets, approximately \$13.1 million for working capital and prepaid royalties, and eligibility for royalties on net sales and contingent milestones.⁵ These amounts are transaction consideration. They are not prices charged to patients, a valuation of clinical benefit, or a regulatory penalty. The announcement described royalties of 7.5%-8% over twenty years, subject to contractual conditions, plus minimum royalties and milestones.⁵

The December 2022 announcement presented the proposed transaction as a way to reduce financial obligations and move toward a royalty model.⁴ That stated rationale helps explain the business decision; it does not establish that the transaction reduced treatment costs. In analytical terms, a royalty arrangement can preserve the original developer's economic exposure to sales while transferring marketing and distribution decisions to another organization. Determining an actual effect on affordability requires evidence about the commercial partner's practices and payer arrangements.

The \$200,000 SEC penalty belongs in yet another category: a civil sanction for disclosure violations.¹ Comparing it mechanically with transaction proceeds would combine different dates, purposes, and economic measures. No such ratio is used here. The report instead makes the missing evidence visible so that readers do not mistake a readily available financial number for a direct measure of patient access.

5. Outcomes, the company's position, and current status

The completed SEC matter includes the civil penalty, the cease-and-desist order, and the recorded remedial steps. The reviewed record does not establish a criminal conviction of TherapeuticsMD arising from those selective disclosures. The company accepted the settlement without admitting or denying findings.¹ That qualification defines the legal status of the resolution.

The Mayne transaction closed on December 30, 2022. The company announced completion on January 3, 2023 and stated that proceeds were used in part to repay financing obligations and redeem preferred equity.^{5,6} Describing this as a sale of TherapeuticsMD itself would be inaccurate: the transaction concerned specified assets and commercial rights while the public company continued with a different economic model.

The subsequent relationship became disputed. The 2025 annual report, filed in March 2026, describes competing lawsuits concerning working-capital allowances and contractual issues. Both sides advanced claims that included fraudulent inducement; the report described magistrate-judge recommendations concerning dismissal of some claims.⁷ Allegations in those proceedings must remain attributed to the parties. The word “fraudulent” in a claim's name is not evidence that a court found fraud.

The August 11, 2026 quarterly filing provides a later procedural update: on May 20 the court overruled TherapeuticsMD's objections and directed submission of working-capital claims to the contractual dispute-resolution process, while the case was stayed pending expert determination. The filing continued to describe disputed demands and uncertainty over potential loss. It also reported substantial doubt about the company's ability to continue as a going concern.⁶ These updates supersede a description that stops at the March recommendations.

A going-concern warning expresses uncertainty about financial continuity under stated conditions. It is not, by itself, a bankruptcy filing, proof of insolvency on every legal measure, or evidence that all licensed products disappeared from pharmacies. Because commercialization is performed by partners, the company's financial position and the immediate availability of a medicine are connected but distinct questions.

The report relies on the filing for the current litigation description rather than independently reconstructing every docket entry. That choice is made explicit because the filing represents TherapeuticsMD's account. It provides a reliable source for what the company disclosed, but it is not a substitute for examining opposing pleadings or a final decision if a detailed litigation conclusion is required.

As of the research check, the appropriate current profile is therefore a continuing royalty company with unresolved commercial disputes and disclosed liquidity uncertainty. The 2017 conduct and 2019 SEC outcome remain important history. They should not be used to imply that the company's current structure, products, or legal posture have remained unchanged for nine years.

6. Implications, methodology, and boundaries

The main governance implication is practical: communication controls need to cover informal follow-up, not just scheduled public announcements. In a development-stage pharmaceutical business, a seemingly qualitative description of an FDA meeting can alter expectations materially. A robust process would identify who can speak, what information is already public, how new information is reviewed, and how an accidental selective disclosure is corrected. These are analytical implications of the SEC's documented sequence, not a certification of any company's present compliance program.

The access implication is different. Women's health products can face reimbursement barriers after FDA approval, while changes in licensing may make it harder for an outside reader to identify who controls commercialization. A useful public report should name the current commercial relationship and separate it from the original developer. It should also avoid implying that one company's royalty revenue reveals what a patient paid for a medicine.

This report used the SEC's order as the principal source for findings and disposition, the SEC announcement as a concise cross-check, historical and current company filings for business context, and transaction announcements for the parties' stated purpose and terms. Seven primary sources were opened and relevant passages reviewed. The latest-status search included the August 2026 quarterly filing. It did not treat search-result snippets as the sole support for central allegations or outcomes.

Several boundaries remain. No patient-level dataset was reviewed. No current insurance plan survey or pharmacy price comparison was performed. No original clinical trial reanalysis was conducted, and nothing here recommends a treatment. The report does not infer that a reimbursement obstacle caused a particular health outcome. It also does not estimate total investor loss from the stock movements described by the SEC.

Remaining evidence gaps include the final result of the Mayne dispute, any material change to the royalty company's status, and a dated access study that distinguishes coverage from actual patient expense. A later filing could supersede the procedural description in this account. An assessment of clinical safety would require the relevant FDA reviews, current labeling, and appropriate original research.

The conclusion is deliberately specific. TherapeuticsMD has a documented settled disclosure-enforcement case and a materially changed business model. The sources support criticism of selective information access and scrutiny of current financial and licensing conditions. They do not support a sweeping claim that its women's health portfolio was fraudulent. Preserving that distinction makes the report more useful: readers can see what happened, how it was resolved, what changed, and which important questions remain unanswered.

References

1. U.S. Securities and Exchange Commission. *In the Matter of TherapeuticsMD, Inc., Release No. 86708: Order Instituting Cease-and-Desist Proceedings, Making Findings, and Imposing Civil Penalties and a Cease-and-Desist Order*. 20 August 2019. [Open source](#)
2. U.S. Securities and Exchange Commission. *SEC Charges TherapeuticsMD With Regulation FD Violations*. 20 August 2019. [Open source](#)
3. TherapeuticsMD, Inc. *Form 10-K for the year ended December 31, 2018*. 2019. [Open source](#)
4. TherapeuticsMD, Inc. *TherapeuticsMD Announces Definitive Agreements to License Its Products to Mayne Pharma*. 4 December 2022. [Open source](#)
5. TherapeuticsMD, Inc. *TherapeuticsMD Completes Transaction to License Its Products to Mayne Pharma*. 3 January 2023. [Open source](#)
6. TherapeuticsMD, Inc. *Form 10-Q for the quarter ended June 30, 2026*. 11 August 2026. [Open source](#)
7. TherapeuticsMD, Inc. *Form 10-K for the year ended December 31, 2025*. 30 March 2026. [Open source](#)