

Philip Morris International: Sequencing the U.S. Smoke-Free Portfolio

Internal ID: S&F-STR-450

Topic: Capital Allocation, Competitive Strategy, Innovation

Industry: Tobacco

Source: Strategy & Finance

Publication date: 5 October 2026

License: Not specified

Decision date and information cutoff: October 2, 2026, 4:00 p.m. Eastern Time

Decision scope: Sequence U.S. investment among ZYN expansion, a future IQOS ILUMA launch, or a staged approach

Case convention: This is a hypothetical management decision exercise. The alternatives and assignment are author-created; no private meeting, board budget, or management deliberation is represented.

The decision

In July 2026, Philip Morris International (PMI) reported a mixed first-half record for ZYN in the United States. First-half shipments declined year over year, while second-quarter shipments edged higher and management described offtake as flat to slightly growing. PMI attributed some of the shipment decline to distributor and trade inventory movements and an unfavorable prior-year price and promotion comparison. It also cited uneven competition. These were management explanations; public disclosures did not isolate consumer demand, inventory, pricing, supply, and share effects. [S1]-[S2]

At the same time, PMI had two different U.S. growth paths to consider. It had begun shipping lower-priced ZYN ULTRA variants and received a narrowly scoped FDA authorization for a modified-risk claim on specified ZYN products. Its newer IQOS ILUMA heated-tobacco system remained under FDA review. PMI had a limited Austin rollout of an older IQOS 3.0 blade system, but its regulatory status did not transfer to ILUMA. [S1], [S3]-[S5]

PMI planned to increase U.S. investment in the second half of 2026 to support the expanded ZYN range and prepare for ILUMA. Public materials did not disclose a product-level budget, U.S. product margins, or an ILUMA launch date. [S1]-[S2]

Assignment: Advise PMI's management team on how to sequence incremental U.S. investment over the next planning cycle: prioritize ZYN expansion, prioritize launch readiness for IQOS ILUMA, or stage investment across both. State what evidence should trigger more investment, a pause, or a change in sequencing. Address the strongest case against your recommendation. Distinguish observed results from management explanations and identify the missing information that could change your view.

Use only information public by October 2, 2026, 4:00 p.m. ET. Do not assume a budget, product margin, launch date, switching rate, or regulatory outcome unless clearly labeled as a hypothetical assumption.

The U.S. portfolio and its different clocks

PMI's U.S. smoke-free portfolio placed ZYN nicotine pouches and IQOS heated tobacco at different stages of commercialization and regulatory review. ZYN already had scale and an expanded set of variants. The FDA had authorized marketing of 20 named ZYN variants under its premarket tobacco product application (PMTA) process in January 2025. PMI began first shipments of ZYN ULTRA 9mg and 11mg moist variants in June 2026, positioning them at a lower price per pouch than its flagship dry range. [S1], [S3]

In June 2026, FDA issued modified-risk tobacco product (MRTP) orders permitting this statement for ten named ZYN flavors in 3mg and 6mg strengths: "Using ZYN instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis." The order did not include the newer ULTRA 9mg and 11mg variants. The PMTA marketing authorization and MRTP claim permission are distinct regulatory actions. The MRTP orders require postmarket surveillance and studies, last five years unless renewed, and may be withdrawn. They do not authorize a general "safe" or cessation claim. FDA states that no tobacco product is safe, that complete cessation of tobacco and nicotine is most beneficial, and that completely switching from cigarettes to authorized pouches may reduce exposure to many harmful chemicals in cigarettes. [S4]-[S5]

PMI held U.S. IQOS commercialization rights and had started a limited Austin sale of IQOS 3.0 in March 2025. IQOS 3.0 is a blade-based system. PMI's bundled ILUMA PMTA and MRTP submissions had been accepted for FDA review in March 2024; ILUMA authorization remained pending in PMI's latest annual filing. The earlier blade system's FDA status was not authorization for ILUMA. International IQOS results demonstrated an operating platform, but they did not establish U.S. launch demand or unit economics. [S2], [S6]

Exhibit 1. Commercial and regulatory status at the cutoff

Product/path	Commercial position	FDA position relevant to the decision
ZYN flagship variants	Established U.S. pouch business; PMI reports shipments and management-defined offtake	PMTA marketing authorization for 20 named products. MRTP orders cover ten named flavors at 3mg and 6mg with a specific claim and postmarket conditions.
ZYN ULTRA	First shipments of 9mg and 11mg moist variants began June 2026; lower price per pouch than flagship dry products	Not included in the disclosed ZYN MRTP product list. Do not extend the authorized claim to ULTRA.
IQOS 3.0	Limited Austin rollout began March 2025; blade-based device	Older blade-system authorizations do not establish ILUMA status.
IQOS ILUMA	PMI preparing for potential U.S. launch	Bundled applications accepted for review; authorization remained pending at the cutoff.

ZYN: shipments, offtake, and the investment question

PMI reported 2.9 billion U.S. ZYN pouches shipped in Q2 2026, up 1.8% year over year. For the first half, it reported 5.2 billion pouches, down 11.2%. Total U.S. oral smoke-free product shipments were also down year over year for the first half. The Q2 figure does not, by itself, erase the first-half decline. Shipments are sales into the trade, not a direct measure of consumer purchases or use. [S1]

PMI said Q2 ZYN offtake was flat to slightly higher in a growing category. “Offtake” is a management-defined measure and should be kept distinct from shipments. Management said Q1 shipments had been affected by distributor and trade inventory movements and by a prior-year pricing and promotion comparison. It described competition as uneven. The public information does not independently quantify each factor or provide a full shipment-to-retail reconciliation. [S1]

The product and claims decisions create both opportunity and operating constraints. A broad ZYN push could support distribution, new flavors, and the ULTRA range, while the FDA-authorized statement applies only to named 3mg and 6mg products. ULTRA’s lower price per pouch may widen the offer, but PMI did not report ULTRA-specific uptake, repeat purchasing, margins, or promotional costs. The recent U.S. segment results also showed pressure: Q2 net revenues were down 0.9% organically and gross profit down 8.9% organically. PMI attributed the gross-profit decrease in part to higher manufacturing costs associated with footprint expansion. These segment totals include more than ZYN and do not reveal ZYN’s contribution economics. [S1]-[S2]

Competition and measurement boundaries

Altria’s Q2 2026 filing reported on! at 14.4% of the nicotine-pouch category, pouches at 59.9% of the broader oral-tobacco category, and on! at 8.6% of that broader oral category. These three percentages have different numerators and denominators. The figures are Circana estimates from sampled key trade channels, not a census of all retail. Altria’s broader oral category includes moist smokeless tobacco and all oral pouches; its volume measure counts cans, with one pouch can counted as one moist-smokeless-tobacco can regardless of pouch count. [S7]

Altria also reported that on! PLUS had expanded to 120,000 stores. These measures indicate a competitive presence, not consumer retention, profitability, or a direct comparison with PMI’s pouch shipments. PMI shipment data and Altria’s panel shares use different measurement bases and should not be combined as if they were a common market-share series. [S7]-[S8]

The category’s growth also does not reveal where users came from. Possible pathways include complete replacement of cigarettes, dual use, switching from another smoke-free product, or new nicotine use. Those pathways have different commercial and population implications. Company shipments, retail panels, or trial intentions alone cannot distinguish among them.

What the research can-and cannot-say

Repeated U.S. survey data show that pouch use increased from 2022 to 2024 among adults with current or former cigarette or vaping histories. The study is observational, covers a defined population, and does not estimate whether pouch use caused cigarette cessation or switching. [A1]

A randomized experiment with 47 young adults who used inhalable nicotine and were not planning to quit found that exposure to a modified-risk claim increased stated pouch-use

intentions and the number of diseases participants perceived as less harmful than cigarettes. But the tested wording was adapted from an FDA-authorized General Snus claim, not the later ZYN-specific order. The pouches were repackaged and debranded, and actual enrollment was below the planned sample for the flavor-by-claim interaction. The study measured immediate perceptions and intentions after product tasting-not actual purchases, sustained use, cigarette substitution, cessation, youth behavior, or response to the authorized ZYN package. It cannot be used as a demand forecast. [A2]

FDA's 2025 National Youth Tobacco Survey estimated current pouch use among 1.7% of middle and high school students; among current youth pouch users, 17.6% reported daily use. ZYN was the most commonly reported brand. These survey findings are not evidence that PMI marketing caused youth use, and brand reporting is not market share. They are relevant to the need for monitoring and regulatory risk management. [S9]

The broader scientific literature remains limited for long-term, naturalistic health outcomes and individual transitions between products. A review describes possible harm-reduction potential while calling for more real-world evidence and independent verification. None of the cited studies estimates PMI-specific returns, the causal effect of ZYN marketing, or the profitability of choosing ZYN over ILUMA. [A3]-[A5]

Three hypothetical approaches

1. **Prioritize ZYN expansion.** Direct the next increment of U.S. resources toward ZYN distribution, product availability, and learning about the expanded range. This could capture near-term category opportunities and use existing retail infrastructure. It also puts greater weight on resolving shipment/offtake divergence, competitive pressure, manufacturing costs, and the limits of the FDA claim authorization.
2. **Prioritize ILUMA launch readiness.** Preserve or increase resources for the eventual ILUMA launch, including capabilities and retailer preparation, while maintaining current ZYN support. This could build a second U.S. platform and use PMI's international operating experience. The trade-off is committing resources ahead of an FDA decision, a launch date, and U.S. demand evidence.
3. **Stage investment across both.** Fund selected, measurable ZYN tests and maintain reversible ILUMA readiness work, then release further resources as regulatory, commercial, and operating evidence arrives. This could limit irreversible commitments while preserving options. It may also dilute execution or delay a time-sensitive opportunity. The company has not disclosed the relevant budget or lead times.

Each option should be evaluated against incremental contribution after product, promotional, manufacturing, distribution, compliance, and postmarket costs. Public disclosures do not provide enough product-level data for a point valuation. Students may use scenario assumptions, but should label them and show how the recommendation changes when those assumptions vary.

Questions for discussion

1. Which path should receive the next increment of U.S. investment, and why? What is the strongest argument against your choice?
2. How should PMI interpret the gap between first-half shipments and Q2 shipments and offtake? Which additional measures would distinguish inventory timing from changes in consumer demand or competition?

3. What role, if any, should the ZYN MRTTP order play in the commercial plan? How should management keep the authorized 3mg/6mg variants separate from ULTRA 9mg/11mg?
4. What can the limited IQOS 3.0 Austin rollout and international IQOS results tell PMI about ILUMA? What remains unknown because ILUMA is pending and the U.S. evidence is limited?
5. What indicators and decision gates would you set for repeat demand, price/mix, manufacturing cost, retailer execution, complete switching, youth monitoring, and regulatory progress? Which indicators are leading and which arrive too late to guide investment?
6. What evidence would distinguish complete cigarette replacement from dual use, switching from another smoke-free product, or new nicotine use? What conclusions should the company avoid making from shipments or short-term intentions?

Sources and conventions

Company shipment, financial, and strategy statements are attributed to PMI. Altria competitor metrics are attributed to Altria and retain its panel and denominator definitions. FDA statements describe product-specific orders and surveillance conditions. “Offtake” is management-defined and is not used as a synonym for shipment. The academic studies are used only within their populations, designs, and measured outcomes. No inference is made that nicotine products are safe, that marketing caused youth use, or that any product causes cessation. This case is a strategy exercise, not medical advice or a consumer product recommendation. All evidence is limited to information public by October 2, 2026, 4:00 p.m. ET.

[S1] PMI, [Q2 and first six months 2026 Form 10-Q](#), “U.S. Smoke-Free Shipment Volume,” pp. 57-58 / HTML lines 2374-2382.

[S2] PMI, [2026 Second-Quarter and First Six-Months Results](#), July 22, 2026, U.S. segment and smoke-free highlights.

[S3] PMI, [2025 Form 10-K](#), “Smoke-Free Products,” “U.S. Commercialization,” and “FDA Authorization Process and Status of PMI SFPs,” pp. 47-54 / HTML lines 1436-1448 and 1541-1582.

[S4] FDA, [Marketing granted orders for 20 ZYN nicotine pouch products](#), January 16, 2025; see also [order letter](#).

[S5] FDA, [ZYN modified-risk claim authorization](#), June 30, 2026, product list, exact claim, conditions, term, and cautions.

[S6] FDA, [Modified Risk Granted Orders](#), IQOS 3.0 system entries; compare with PMI’s 2025 Form 10-K [S3] for ILUMA status.

[S7] Altria, [Q2 2026 Form 10-Q](#), oral tobacco share and volume discussion, pp. 52-53 / HTML lines 2136-2163.

[S8] Altria, [Q2 and first-half 2026 results](#), “Smoke-Free Portfolio Update,” lines 52-56.

[S9] FDA, [2025 National Youth Tobacco Survey findings](#), nicotine pouch findings.

[A1] Gravely et al., [U.S. ITC Smoking and Vaping Survey study](#), *Tobacco Control* (published online 2025), abstract and structured results; observational survey of adults with cigarette/vaping histories.

[A2] Vogel et al., [Randomized trial on nicotine pouch claims and use intentions](#), *Tobacco Control* 34(3) (2025):315-322, Methods, results, and discussion.

[A3] Felicione et al., *Oral Nicotine Pouches: Rising Popularity and State of the Science*, *Public Health Reports* (2025), abstract and introduction.

[A4] He et al., *U.S. oral nicotine pouch prices and sales, 2021-2024*, *Tobacco Control* (2025), abstract.

[A5] Levy et al., *Competition and firms' incentives to promote harm-reduction products*, *Nicotine & Tobacco Research* 25 (2023):1810-1821, abstract and summary.