The Category 2 Peptide Unwind: How a Rogan Appearance, 14 Withdrawn Nominations & a July PCAC Docket Will Reprice the Compounding Pharmacy Stack, GLP-1 Gray Market, and Longevity Clinic Supply Chain

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Abstract

- RFK Jr. announced on Feb 27, 2026 (JRE #2461) that ~14 of the 19 peptides the FDA shoved into Category 2 in Sept 2023 would be reclassified back to Category 1.

- As of April 2026, zero of that has hit the Federal Register. Five peptides (CJC-1295, Ipamorelin, Thymosin Alpha-1, AOD-9604, Selank) got yanked from Cat 2 in Sept 2024 and referred to PCAC. PCAC reviewed them on 10/29/24 and 12/4/24 and mostly voted AGAINST 503A bulks list inclusion.

- The actual legal mechanism: nominator withdraws > FDA can still refer to PCAC > PCAC non-binding vote > FDA publishes 503A bulks list update > Federal Register notice. Nothing binding until step 4.

- Next live catalyst: July 2026 PCAC meeting reviewing a larger batch of peptides (the “12 peptides” referenced in the Kennedy post).

- Market context: U.S. compounding pharmacy TAM ~$6.57B in 2024, 503A ~73% share. Compounded GLP-1 slice alone projected $6–8B/yr at peak. Peptide-specific gray market estimated ~$328M in 2025. Peptide therapeutics projected $49.7B globally in 2026.

- 1,000+ adverse events reported on compounded GLP-1s by mid-2025. BPC-157 flagged for immunogenicity risk. ~8% of “research use only” peptide samples tested show endotoxin contamination.

- The investable asks: (1) who owns the API supply chain for peptides crossing back to Cat 1, (2) who owns the telehealth + med-spa dispensing rails, (3) who wins on quality

signal (503B outsourcing facilities w/ cGMP), (4) who gets squeezed (brand-name manufacturers w/ overlapping indications, gray-market importers).

- Bottom line: The Kennedy post is a policy signaling event, not a rule change. The edge is in reading the PCAC calendar, the do
3469), and the peptide-by-peptide scientific

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Part 1: The post, the podcast, and why Feb 27 matters more for calendars than for law

On Feb 27, 2026, Kennedy went on Rogan (JRE #2461) and told the audience that roughly fourteen peptides were coming back. Within 72 hours every longevity clinic Twitter account, every peptide vendor running a Shopify store, and every compounding pharmacy sales rep had pushed the same screenshot. The tweet he posted the next day was more specific: twelve peptides, withdrawn nominations, restoration of access "within weeks."

“Within weeks” is doing a lot of work in that sentence. As of mid-April 2026, the FDA has not published a Federal Register notice modifying the 503A bulks list. The Category 2 list has not been formally revised. No statutory change has passed Congress. LumaLex and Buchanan Ingersoll (among the more sober compounding-law shops) both published essentially the same analysis: the policy direction is real, the rulemaking is not.

> So what actually happened? Three things, and it is worth separating them because confusing the three is where most operators lose money.

First, on Sept 20, 2024, the FDA formally removed five peptides from Category 2: CJC-1295, Ipamorelin acetate, Thymosin Alpha-1, AOD-9604, and Selank acetate. The trigger was that the original nominators withdrew their nominations. Withdrawal does not equal approval. Removal from Cat 2 means the peptide is no longer actively flagged as a safety concern under interim policy, but it still cannot be compounded under 503A unless it appears on the bulks list, has a USP monograph, or is the active ingredient in an FDA-approved drug. None of which applies to these five.

Second, PCAC (the Pharmacy Compounding Advisory Committee) actually convened and voted. Oct 29, 2024 covered Ipamorelin, Ibutamoren, and Kisspeptin-10. Dec 4, 2024 covered CJC-1295, Thymosin Alpha-1 (acetate and free base), and AOD-9604. The committee voted against recommending most of them for the 503A bulks list. That vote is non-binding, but historically the FDA follows PCAC recs maybe 80%+ of the time. This is the part of the timeline that does not appear in any of the LinkedIn posts about “peptides are back.”

Third, Kennedy’s Feb 27 announcement reflects a political intent to override or reroute the PCAC outcome. That is the actual news. The administration is signaling it wants the FDA to apply a different safety-signal standard and move a larger basket of peptides through the pipeline in one go, with the July 2026 PCAC as the next formal forum.

> The Rogan clip did one useful thing for investors: it set a date-certain for a catalyst. The July PCAC meeting now has attention on it that it would not otherwise have had.

Part 2: What Category 2 actually is, and why compounding pharmacy people lost their minds in Sept 2023

Quick refresher, because the category system is bad at being self-explanatory. Under the Drug Quality and Security Act of 2013 (the meningitis-outbreak law), compounding happens in two lanes: 503A (traditional pharmacy, patient-specific Rx, state-board oversight, no cGMP, no FDA approval required) and 503B (outsourcing facility, bulk production without patient-specific Rx, FDA-registered, cGMP-compliant).

Inside 503A, a pharmacy can compound a substance if one of three conditions holds: the substance has a USP or NF monograph, it is the active ingredient in an FDA-approved drug, or it appears on the 503A bulks list. Most peptides satisfy none of those. To get on the bulks list, someone has to nominate the substance, FDA evaluates it on four criteria (physicochemical characterization, safety, effectiveness evidence, historical use in compounding), PCAC reviews and votes, then FDA publishes a final rule.

While all that is happening, the FDA sorts nominated substances into interim buckets. Category 1 means "under evaluation, no significant safety risk identified, enforcement discretion applies." Category 2 means "potential safety concerns identified, no enforcement discretion, do not compound this." There is technically a Category 3 for procedurally disqualified nominations. For practical purposes, Cat 1 = green light, Cat 2 = red light.

On Sept 29, 2023, FDA dropped nineteen peptides into Category 2 in a single move. Overnight, BPC-157, TB-500, CJC-1295, Ipamorelin, AOD-9604, Thymosin Alpha-1, GHK-Cu, Semax, Selank, KPV, MOTS-c, Epitalon, LL-37, Melanotan II, Kisspeptin-10, GHRP-2, GHRP-6, PEG-MGF, and DSIP became effectively uncompoundable. A multi-hundred-million-dollar slice of the compounding pharmacy business went dark in a week.

The stated reasons on the FDA side were consistent across the briefing docs: immunogenicity risk (peptides can trigger anti-drug antibodies, especially with repeated injection), manufacturing impurity concerns (peptide synthesis is notoriously sensitive to endotoxin contamination, truncated sequences, and diastereomers), and lack of robust human clinical data. The last one is the most honest. For most of these molecules, the human evidence base is a few small case series, a handful of underpowered trials conducted outside the U.S., and a lot of anecdotal reporting from longevity clinics.

The industry response was about what you would expect. The Outsourcing Facilities Association and a handful of 503A plaintiffs filed suit. At least one of those suits settled, with the FDA agreeing to route the contested peptides through PCAC rather

than leave them stranded in Cat 2 indefinitely. That settlement is the quiet reason five peptides moved in Sept 2024. It was not benevolence. It was litigation.

Part 3: The withdraw-then-refer trick, and why it is not new

The mechanism Kennedy references, nominators withdrawing nominations and FDA responding by moving the substance from Cat 2 to PCAC review, is not a novel maneuver. Read the Oct 2024 and Dec 2024 PCAC briefing books and the pattern jumps off the page.

Here is what actually happens. A nominator (usually a compounding pharmacy trade group or a specialty API supplier) submits a nomination for inclusion on the 503A bulks list via the public docket (FDA-2015-N-3534 for 503A, FDA-2015-N-3469 for 503B). FDA reviews, finds gaps in the safety or efficacy data, and proposes Cat 2 status. The nominator then has a choice: withdraw, supplement with more data, or let FDA propose adverse action.

If the nominator withdraws, FDA has two options. It can let the substance fall out of the active process entirely (in which case it cannot be compounded under 503A regardless, because it still does not appear on the bulks list). Or it can elect to proceed to PCAC review on its own initiative. The Dec 2024 briefing document explicitly says "this nomination was withdrawn, however, FDA is electing to proceed to PCAC review," for multiple peptides.

Why would FDA proceed after withdrawal? Usually because the substance has enough clinical traction, public attention, or regulatory pressure that a definitive PCAC record is useful. A PCAC "no" vote is easier to defend in future litigation than an abandoned nomination with no record.

What is new in 2026 is not the mechanism. It is the batching. Kennedy is signaling that twelve peptides will run through this process more or less simultaneously, with the July 2026 PCAC as the forum. That is procedurally unusual but not unprecedented. The political theater around it (HHS Secretary, Rogan, coordinated clinic marketing) is what is actually new.

For anyone underwriting a deal in this space, the takeaway is that the procedural path is well-defined and slow. Even under a maximally favorable PCAC outcome in July, a final Federal Register notice updating the bulks list typically trails the advisory vote by four to nine months. Full rulemaking with notice and comment can push that to

twelve to eighteen months. The clinics running ads saying “peptides are back, order today” are, at best, overselling the timeline by two to three quarters.

Part 4: PCAC’s Oct and Dec 2024 votes, and the uncomfortable scoreboard

> The Oct and Dec 2024 PCAC meetings are the part everyone glosses over, because the results are inconvenient for the bull case.

October 29, 2024: Ipamorelin, Ibutamoren, and Kisspeptin-10. FDA came in with the default recommendation of “not include on 503A bulks list.” PCAC voted against inclusion for most of these. The stated concerns were the usual suspects: insufficient human safety data, mechanistic concerns about unintended endocrine effects, and a lack of reproducible efficacy data outside of small or open-label trials.

December 4, 2024: CJC-1295, Thymosin Alpha-1 (acetate and free base), and AOD-9604. Same structural outcome. PCAC voted against inclusion. The Thymosin Alpha-1 discussion is worth flagging because it has the strongest human clinical evidence of any molecule on the list. It has been used clinically in over 35 countries. It has published data in hepatitis, sepsis-adjacent indications, and immune reconstitution. And it still got voted down, largely because the committee concluded the U.S. evidence base was not equivalent to international use.

The implication for the Feb 2026 announcement is uncomfortable. Kennedy is proposing to reclassify peptides that the actual scientific advisory committee, hearing sworn expert testimony and reviewing the safety data packages, voted against less than fifteen months ago. One of two things has to happen for the political timeline to hold: (a) the PCAC panel gets reconstituted with members more sympathetic to the regulatory-arbitrage view (which has partially happened already; the PCAC membership was adjusted in 2025), or (b) the FDA bypasses PCAC recommendations and issues a final rule contrary to the advisory vote. Option (b) is legally possible but historically rare and invites immediate litigation from patient-safety groups and brand manufacturers.

The smart money is underwriting option (a) with a haircut. Assume PCAC gets more sympathetic, assume the July 2026 vote is closer to 50/50 than the 2024 votes, and assume FDA issues a split decision: maybe five to seven peptides get reclassified to Cat 1, the rest stay in Cat 2 with specific safety objections documented. That is a materially different outcome from “14 peptides are back,” and it matters a lot for anyone running inventory forecasts on an API purchase order.

Part 5: The peptide list, graded by PCAC survivability

Here is the rough-cut handicap, based on the briefing docs, the 2024 PCAC votes, and the public safety record. This is not investment advice and the list will move with the July 2026 docket. Grades are a subjective read of primary objections.

Likely to clear, with caveats. Thymosin Alpha-1 has the strongest international clinical record. The 2024 no-vote was about U.S. evidence, not mechanistic concern. A cleaner data package could flip it. AOD-9604 has a relatively clean safety profile and was originally developed as an anti-obesity agent that made it through Phase 2 before being dropped for commercial rather than safety reasons. GHK-Cu has decades of topical cosmetic use and a reasonable safety record, though the injectable use case is less well-characterized. Selank has Russian clinical use but limited U.S. data, and may clear on historical-use grounds alone.

Contested middle. BPC-157 is the most-demanded molecule on the list and the most likely to attract a political push, but FDA has specifically flagged immunogenicity risk, and the evidence base is almost entirely animal (rat tendon models, rat GI models) with very limited human data. The FDA's objection here is concrete and hard to rebut without new clinical data, which nobody has generated because the market has been running on compounded product. TB-500 / Thymosin Beta-4 has similar issues. CJC-1295 and Ipamorelin already got voted down; they would need a reconstituted panel or new data to clear. KPV and MOTS-c are niche enough that they may clear on "nobody is hurt by these" grounds, but the efficacy data is genuinely thin.

Unlikely to clear. Melanotan II has real cardiovascular signals, nausea, and the melanoma-adjacent cosmetic use case, which makes FDA uniquely hostile. GHRP-2 and GHRP-6 have complex side effect profiles (cortisol and prolactin elevation, strong appetite stimulation). DSIP and Epitalon have essentially no rigorous clinical data. LL-37 has mechanistic concerns related to its role in autoimmunity. Kisspeptin-10 has endocrine effects that make FDA nervous in a general-population compounding context.

Semax is the wildcard. Strong Russian evidence, interesting nootropic claims, and a defensible safety record, but almost no U.S. data. Could go either way on the July docket.

The practical upshot for an angel deciding whether to write a check into a peptide-adjacent startup: if the business model requires BPC-157 or TB-500 to be legally

compounded at scale in the U.S. inside the next 18 months, haircut that assumption hard. If the business model works at a subset of five to seven peptides clearing, there is an actual opportunity.

Part 6: The compounding pharmacy stack, post-GLP-1 unwind

Context matters here, and the GLP-1 unwind is the closest analogue to what is about to happen with peptides. Both show how fast compounding pharmacy economics can flip.

The U.S. compounding pharmacy market was ~$6.57B in 2024 across all therapeutic areas, with 503A representing roughly 73% of revenue. At peak GLP-1 shortage, compounded semaglutide and tirzepatide represented $6–8B of annualized revenue, with roughly 4–5M compounded Rx per year by some estimates. Then FDA declared the shortages resolved (tirzepatide in Dec 2024, semaglutide in Feb 2025), the 503B wind-down hit in May 2025, and the 503A guidance tightened shortly after.

What happened next is instructive. The 503B facilities mostly exited GLP-1 compounding (under court order). The 503A pharmacies pivoted to the “clinical difference” exemption, which lets them compound technically-not-a-copy versions (different concentrations, added B12, peptide cocktails, microdose protocols). FDA sent a wave of warning letters. State boards got overwhelmed. Several telehealth platforms lost distribution relationships. Manufacturer cease-and-desist letters multiplied. The gray market for “research-use-only” peptides (including non-GLP-1 peptides) filled part of the gap.

The adverse event count on compounded GLP-1s crossed 1,000 by mid-2025. That is the number the FDA keeps pointing at in rulemaking. For context, brand-name semaglutide generated 8,000+ adverse events in 2023 alone per FAERS, on a much larger prescription base, but the per-prescription rate comparison is not clean because compounded AE reporting is patchier.

The peptide reclassification, if it happens, would ride on top of that compounding stack. The players who survived the GLP-1 unwind with their licenses intact (Empower, Hallandale, Olympia, a handful of regional 503Bs) are the ones positioned to catch peptide volume. New entrants face a brutal barriers-to-entry problem: 503B registration takes 18–24 months, state 503A licenses are a patchwork, and cGMP compliance is expensive.

The angel-check question is whether the peptide wave creates room for a new vertical compounder, or whether the existing platforms soak up all the volume. The historical evidence says the incumbents win because they have the API supplier relationships, the state licenses, and the pharmacist relationships with the prescribing clinics. A new entrant needs a differentiator that is not just "we compound peptides too." The interesting angles are on the verification layer (COA aggregation, independent lot testing, supply chain traceability) and on the prescriber software layer (protocol libraries, dosing calculators, compliance documentation).

Part 7: The gray market problem, and why quality signal is the real moat

PeptiDex pegged the gray market for imported peptides at roughly $328M in 2025, and U.S. peptide search volume hit 10.1M queries per month by Jan 2026. Independent testing of "research-use-only" peptide samples found endotoxin contamination in approximately 8% of samples across vendors, with a smaller but nontrivial share containing none of the labeled compound.

That is the actual market reality the Kennedy announcement is trying to address. Demand did not disappear when FDA put peptides in Cat 2. It migrated. Patients who were getting physician-supervised Thymosin Alpha-1 at a legitimate compounding pharmacy in Sept 2023 were, by mid-2024, ordering Chinese-origin product from websites with "research purposes only" disclaimers. Contamination rates went up. Dosing errors went up. Downstream adverse events went up. The FDA ended up with worse safety outcomes, not better.

That is the political argument Kennedy is leaning on, and it is not a bad one. The counterargument, which the FDA career staff makes in briefing docs, is that legitimizing compounding does not solve the contamination problem unless the bulks API supply chain is cleaned up in parallel. Compounded product is only as safe as the API that goes in.

For investors, this is where the interesting structural bet is. Assuming some peptides clear to Cat 1, the new binding constraint becomes API quality. There are a handful of FDA-registered bulk API manufacturers capable of producing pharmaceutical-grade peptides (Bachem, Polypeptide, CordenPharma, Auspep, and a few specialty players). Most U.S. compounding is currently running on imported API from Chinese suppliers with uneven USP compliance and variable COA quality.

If a peptide gets 503A-eligible, the compounding pharmacy is required to source from an FDA-registered API manufacturer with documented cGMP compliance. That

constraint immediately prices out a chunk of the current gray-market API supply. The surviving suppliers get pricing power. The downstream consequence is that legitimate compounded peptides will land at roughly $150–400 per month retail, which is 3–8x the gray market price but still materially cheaper than most branded alternatives (where one exists).

That is a pricing environment where a quality-signal brand matters. “Sourced from FDA-registered facility, lot-specific potency and sterility testing, cGMP-compliant fill/finish” becomes a differentiator the prescriber can point to. For a startup building in this space, owning the quality signal is probably a more defensible position than owning the distribution.

Part 8: Where angel and seed checks actually compound from here

Running through the zones where capital can meaningfully move the needle in the next 18 months, with the understanding that all of this is contingent on FDA actually publishing something:

API verification and lot traceability. Every compounding pharmacy is going to need defensible documentation on where their peptide API comes from, what the COA shows, and whether the lot passes independent potency and endotoxin testing. The current workflow is manual, PDF-based, and error-prone. A SaaS layer that sits between the API supplier, the pharmacy, and the prescriber, handling COA intake, anomaly detection, and audit trail, has a clear buyer (the pharmacy operator, because state board audits are getting more aggressive) and a clear wedge (existing tools are terrible). The problem is that the TAM is narrower than it looks; there are maybe 3,000–5,000 compounding pharmacies nationally, and only a subset will touch peptides.

Prescriber-facing protocol and compliance tools. The med spa and longevity clinic operator has a real problem: keeping track of which peptides are legally compoundable in which states, for which indications, with what documentation, under what insurance posture. A vertical EHR + protocol library + e-prescribing workflow that handles the state-by-state variance, the “clinical difference” documentation, and the informed consent language is a genuinely useful product. Spruce, Akute, and a few others have nibbled at the edges here, but nobody has nailed the peptide-specific workflow. This is probably the highest-probability investable zone.

Telehealth distribution platforms. The incumbents (Hims, Ro, Noom, LifeMD) have the brand, the CAC machinery, and the prescriber network. A pure-peptide DTC entrant faces brutal CAC economics unless it can cross-sell from an adjacent indication. The more interesting model is a B2B play: a platform that powers the independent longevity clinic's telehealth stack, letting a single-location operator offer the same digital intake and follow-up experience as a national brand without building it themselves.

503B outsourcing facility consolidation. There are roughly 70–80 FDA-registered 503B outsourcing facilities. Many of them are undercapitalized family businesses that got squeezed by the GLP-1 unwind. If peptides come back at scale, cGMP-compliant sterile fill capacity becomes a constraint. A roll-up play in 503B sterile compounding, capitalized to $50–100M, is not an angel check, but the ancillary businesses (QA software, environmental monitoring, sterility assurance, BUD extension studies) are all angel-checkable. This is also the quietest part of the market and the one where operators with actual pharmacy experience have a massive information edge over generalist investors.

Peptide-specific clinical evidence generation. The honest bull case for long-term peptide market expansion is that someone eventually runs the Phase 2/3 trials that FDA keeps saying are missing. A CRO or investor-backed platform that runs well-designed real-world-evidence studies or small RCTs on the highest-demand peptides (BPC-157 in tendon repair, Thymosin Alpha-1 in immunocompromised populations, KPV in IBD) could generate the data package that flips the next PCAC cycle. This is a longer-horizon, harder-to-underwrite bet, but it is the one that actually moves the category out of the compounding gray zone and into a normal drug approval track.

Testing and COA aggregation as a consumer-facing brand. There is a plausible "Carfax for compounded peptides" play where the end patient can verify their specific lot, see third-party testing results, and confirm the pharmacy's license status. This is consumer-grade trust infrastructure in a category that desperately needs it. The hard part is distribution; the easy part is building the product.

Part 9: What to watch between April and Q4 2026

A short list of catalysts that will actually move primary-source documents and therefore reprice assumptions:

Before July, watch the FDA docket (FDA-2015-N-3534 and FDA-2015-N-3469) for briefing book postings. Historically these drop 30–45 days before the PCAC meeting.

The briefing books will tell you which peptides are on the July agenda, which form (acetate vs free base) is being evaluated, and what safety objections FDA is leading with. That is the real information.

Watch the Federal Register for any interim guidance from FDA on the 503A bulks evaluation process. An interim guidance that loosens the "significant safety risk" threshold for Cat 2 designation would be a much bigger deal than any specific peptide reclassification.

Watch the PCAC membership. Additions to the committee in 2025 reshuffled the balance of perspectives. Additional changes before the July meeting would be a strong leading indicator of where the votes are heading.

Watch the 503B outsourcing facility filings. If the handful of cGMP-compliant 503Bs start filing for additional product capabilities that cover peptide APIs, that is a signal they expect volume. These filings are public via FDA's 503B registration database.

Watch for litigation. If the Feb 2026 announcement gets translated into an administrative action that bypasses PCAC or Federal Register rulemaking, expect lawsuits from patient safety groups or from brand manufacturers with overlapping indications (Lilly and Novo have already shown they will sue, and they have competent plaintiff's counsel). Litigation would delay the effective date by 6–18 months.

Watch state pharmacy boards. Even if federal reclassification happens, states can and do impose tighter requirements. California, Texas, Florida, and New York are the four markets that matter. State-level guidance can lag or lead federal action by quarters.

Watch the adverse event count. If the compounded peptide AE count spikes as volumes pick up, expect FDA to reverse or pause. The political cost of a few high-profile harm incidents could crater the entire trajectory in a news cycle.

Part 10: The honest caveats

Nothing in this essay is legal or financial advice. The author is not a lawyer, not a regulatory affairs professional, and not an actual compounding pharmacist. If you are an operator making inventory purchasing decisions, call your regulatory counsel. If you are an investor sizing a position, build your own regulatory probability model rather than borrowing anyone else's.

The peptide category has a long history of overpromising and underdelivering on both the clinical side and the regulatory side. BPC-157 in particular has been "three months from reclassification" for approximately four years running. Each cycle draws

in a new wave of operators who get blown up on the next FDA pivot. The Feb 2026 announcement is the most credible signal the category has had, but “most credible” is grading on a curve.

There is also a real safety argument that does not get enough airtime in the enthusiast circles. Peptide injections, even the well-studied ones, do not have the kind of controlled-trial safety data that pharmaceutical investors are used to. Immunogenicity, contamination risk, and off-target effects are not paranoid concerns. They are concerns that killed the nominations in the first place, and they will not disappear because the political wind shifts. The investor who underwrites the most aggressive bull case on peptides should think carefully about what happens if two or three high-profile adverse events hit in the back half of 2026.

The best version of this story is that the policy environment settles into a stable middle ground, where five to seven of the better-characterized peptides clear to Cat 1, the API supply chain tightens up around FDA-registered manufacturers, compounding pharmacies offer legitimate prescriber-supervised access at moderate price points, the gray market shrinks, and a few actual clinical trials get run on the higher-demand molecules. That outcome is good for patients, good for legitimate operators, and good for the handful of investors who position around the middle of the fairway rather than the tails.

The worst version is a chaotic reclassification followed by safety incidents, followed by reversal, followed by a worse gray market than before. That outcome is possible too, and the timeline between those two scenarios is maybe 18 months either way.

The Kennedy post is not a rule. The July 2026 PCAC is not a guarantee. The twelve peptides on the list are not a unified basket; they will split across the safety and efficacy spectrum the same way they did in Dec 2024. Read the briefing books. Read the dockets. Talk to a compounding pharmacist who has actually lived through a PCAC cycle. The edge in this category is not in the tweet. It is in the paperwork nobody wants to read.

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