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AND ENTREPRENEURSHIP

March 18, 2026

Evan Masingill
GenBioPro
Chief Executive Officer
PO Box 32011
Las Vegas, NV 89103

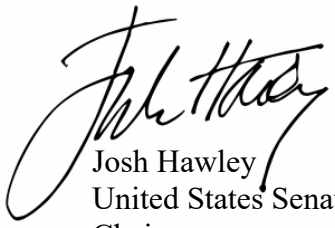
Dear Mr. Masingill:

I write to inform you that I am opening an investigation into GenBioPro and its manufacture, distribution, and marketing practices relating to a generic version of mifepristone. Mounting evidence suggests that mifepristone poses grave risks to women. Yet your company has continued to profit from the widespread distribution of this drug even as serious questions have emerged about hemorrhage, infection, sepsis, and other dangerous complications associated with its use.

These concerns are especially serious because as mifepristone became more widely distributed, your company was in a position to learn far more about the drug's real-world consequences than the public. The larger the market for your product has become, the greater your access to adverse-event information, complication data, provider feedback, pharmacy complaints, and post-market safety signals. Yet serious questions remain about whether your company fully investigated those dangers and accurately conveyed them to regulators and the public. The success of your company's mifepristone business depends on broad distribution and public confidence in the drug's safety, so your company has a powerful financial incentive to avoid facts that could threaten sales, invite scrutiny, or justify stronger safeguards.

Congress must determine what your company knew about the harms associated with mifepristone, when it knew it, what it told regulators, and what it may have failed to disclose to women and the public. Accordingly, please produce the documents and information described in the attached Schedule by no later than April 24, 2026. The women exposed to the risks of this drug deserve a full accounting.

Sincerely



Josh Hawley
United States Senator
Chairman
Subcommittee on Crime and Counterterrorism

## Schedule

### I. Safety, adverse-event, and complication data

1. All adverse-event reports, serious adverse-event reports, case narratives, follow-up reports, and periodic safety reports concerning mifepristone.

2. All internal databases, spreadsheets, dashboards, summaries, signal-detection reports, and analyses concerning adverse events, including but not limited to hemorrhage, sepsis, infection, incomplete abortion, retained tissue, emergency-room visit, hospitalization, transfusion, surgery, ectopic pregnancy, continuing pregnancy, fetal anomaly after failed abortion, and death.

3. All documents reflecting actual or estimated rates of complications, emergency-room visits, hospitalization, surgery, transfusion, ambulance transport, or physician follow-up after use of your company's mifepristone product.

4. All documents sufficient to show what information the company receives, requests, or tracks from prescribers, pharmacies, distributors, telehealth providers, call centers, patient-support services, or third parties regarding complications or outcomes.

5. All analyses comparing FDA label language, Risk Evaluation and Mitigation Strategies ("REMS") disclosures, patient materials, or marketing statements with real-world safety data known to the company.

### II. REMS compliance and postmarketing surveillance

6. All documents concerning compliance with the Mifepristone REMS Program, including prescriber certification, pharmacy certification, Patient Agreement Forms, audit procedures, internal compliance reviews, deviations, violations, corrective actions, and communications with any REMS administrator.

7. All REMS assessments, periodic submissions, internal draft assessments, supporting datasets, and communications concerning the effectiveness of REMS elements.

8. All documents concerning whether the company believed additional REMS elements, stronger screening requirements, or renewed in-person requirements were warranted.

### III. Communications with FDA and other regulators

13. All communications with FDA regarding approval, labeling, REMS, REMS modifications, safety signals, pharmacovigilance, adverse-event reporting, inspections, audits, enforcement, or postmarketing requirements.

14. All communications with FDA relating to the 2021–2023 REMS modifications, including removal of the in-person dispensing requirement and addition of pharmacy certification.

FDA states that applicants submitted supplemental REMS modifications after FDA sent REMS Modification Notification letters.

15. All communications with any state attorney general, state medical board, state pharmacy board, foreign regulator, or other governmental entity concerning the safety, distribution, labeling, or legality of mifepristone.

## IV. Clinical, medical, and scientific analyses

16. All clinical studies, observational studies, meta-analyses, literature reviews, safety reviews, unpublished manuscripts, and internal scientific evaluations concerning mifepristone's safety, efficacy, and complications.

17. All documents concerning cases of ongoing pregnancy, failed abortion, use beyond labeled gestational age, use where ectopic pregnancy was later identified, and any congenital-anomaly or fetal-harm reports following failed abortion.

18. All documents evaluating whether passive adverse-event collection undercounts complications.

## V. Marketing, promotional, and public messaging

19. All advertising, promotional materials, patient-facing materials, prescriber-facing materials, pharmacy-facing materials, call-center scripts, FAQs, website materials, and talking points concerning safety, efficacy, convenience, privacy, or risk.

20. All substantiation documents for claims that the product is "safe," "effective," "well-studied," "comparable" to other products, or appropriate for mail-order or telehealth dispensing.

21. All documents concerning whether known adverse-event or complication data affected marketing claims, public statements, or patient disclosures.

## VI. Manufacturing, quality, and supply chain

22. All documents sufficient to identify each manufacturer, contract manufacturer, packager, relabeler, distributor, fulfillment partner, pharmacy channel, and shipping vendor involved in the manufacture or distribution of your company's mifepristone product.

23. All inspection reports, warning letters, audit findings, deviation reports, corrective-action/preventive-action materials, stability reports, batch-failure reports, and quality complaints relating to mifepristone.

24. All documents concerning changes in manufacturing location, supplier, active pharmaceutical ingredient source, packaging, labeling, or distribution channel.

## VII. Corporate structure, ownership, and financial incentives

25. All documents sufficient to identify the company's current ownership structure, parent entities, affiliates, major investors, and entities with revenue-sharing or profit-participation rights relating to mifepristone.

26. All board materials, investor presentations, strategy memoranda, or internal analyses discussing the profitability of mifepristone, expected revenue, market share, impact of telehealth/mail distribution, or the financial effect of regulatory changes.

27. All documents concerning any effort to obscure or limit public disclosure of company ownership, location, manufacturing relationships, or distribution relationships.

## VIII. Litigation, complaints, and insurance

28. All documents concerning lawsuits, threatened claims, demand letters, patient complaints, pharmacy complaints, prescriber complaints, malpractice allegations, indemnity claims, or insurance notices arising from use of mifepristone.

29. All settlements, tolling agreements, indemnity agreements, and insurance policies that may provide coverage for claims arising from injuries allegedly related to mifepristone.

## IX. Custodians and data preservation

30. A list of all custodians, departments, databases, vendors, and repositories likely to contain responsive material, including pharmacovigilance teams, medical affairs, regulatory affairs, quality, legal, commercial, investor relations, and any third-party REMS or safety vendors.

31. A description of the company's document retention and data preservation practices for adverse-event reports, complaint files, call-center logs, pharmacy data, and communications with prescribers or regulators.