



Agile Therapeutics Provides Update on Actions Being Taken to Strengthen the Affordable Care Act's No-Cost Contraceptive Coverage Requirement

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The Company Commends House Committee on Oversight and Accountability Ranking Member Jamie Raskin for New Report on Contraception Coverage Gaps

New Report Follows Several Months of Activity by the Biden Administration and Lawmakers to Strengthen Access to Contraception as Defined in President Biden's June 2023 Executive Order

Implementation of the Committee's Recommendation Could Potentially Eliminate Financial Barriers for Contraceptive Products like Twirla® for 49 Million Women

PRINCETON, N.J., Dec. 12, 2023 (GLOBE NEWSWIRE) -- Agile Therapeutics, Inc., (Nasdaq: AGRX), a women's healthcare company, today provided an update on the actions being taken to strengthen the Affordable Care Act's (ACA) no-cost contraceptive coverage requirement.

Following several months of focus by the Biden Administration and lawmakers on contraception and reproductive healthcare access barriers, the House Committee on Oversight and Accountability issued a new report addressing the topic: Revised Federal Guidance Regarding Contraceptive Coverage Could Benefit Millions of Women¹. The report highlights the continued barriers to contraceptive care and inequalities that continue to impact women's freedom to access the contraceptive that is best for them.

"We appreciate the continued hard work of the Administration to ensure all women have access to contraceptive care without barriers and cost-sharing," said Agile Therapeutics Chairperson and Chief Executive Officer Al Altomari. "We look forward to seeing the outcomes of this work result in meaningful changes that eliminate the challenges patients and providers face in accessing reproductive healthcare."

The Company commends Rep. Jamie Raskin for his efforts to ensure that women have the healthcare and contraception that they need. Key highlights from the new report include:

- The report reinforces the urgent need for revisions to federal guidance. By implementing the Committee's proposed guidance revisions, the Tri-Departments could potentially ensure that 49 million women of reproductive age have increased access to no-cost contraception.
- The report is a follow-up to, Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance², in which a House Committee investigation found that insurers and PBMs consistently imposed exclusions or cost-sharing requirements for contraceptive products.
- The previous investigation resulted in a recommendation that the administration update guidance to address coverage gaps by requiring that all contraceptives without a therapeutic equivalent (generic) are covered on plan formularies. This would ensure that all people have access to the most appropriate contraceptive products without out-of-pocket payment, as required by the ACA.

This new report follows several recent noteworthy efforts from the Biden Administration and lawmakers to strengthen access to contraception as defined in President Biden's June 23, 2023, Executive Order: Strengthening Access to Contraceptives³. Recent efforts include:

After an investigation led by the state finding systemic non-compliance with contraceptive coverage requirements, Vermont Lawmakers requested the Administration provide additional oversight and enforcement of the ACA Contraceptive requirements to ensure health plans and PBMs are following federal and state guidance.

- In a November 16, 2023, letter⁴ to the Secretaries of the Departments responsible for implementation of the ACA contraceptive coverage requirements; the Congressional leaders from Vermont, Senators Bernie Sanders and Peter Welch and Representative Becca Balint, requested information from the Departments regarding its efforts to enforce the Affordable Care Act's (ACA) no-cost contraceptive coverage requirement.
- The letter highlighted a recent state investigation that found three insurers in Vermont—BCBS VT, MVP Health Care, and Cigna Healthcare—had failed to provide patients with no-cost contraceptive services in violation of state and federal law and resulted in required restitution of almost \$1.5M in inappropriate costs charged to consumers.

The Biden Administration convened several meetings to discuss efforts to ensure robust implementation of the President's Executive Order on Strengthening Access to Contraceptive Care.

- On October 27, 2023, the White House convened private sector leaders to discuss efforts to ensure access to affordable, high-quality contraception⁵. Administration leaders emphasized the importance of continuing to build on the progress that has been made under the ACA. These efforts include robust implementation of the President's third Executive Order on reproductive health care access, issued in June 2023, which directed federal agencies to “ensure coverage of comprehensive contraceptive care, including all contraceptives approved, granted, or cleared by the Food and Drug Administration (FDA), without cost sharing for enrollees, participants, and beneficiaries.”
- On November 8, 2023, the U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra⁶, hosted a roundtable to hear directly from researchers on the ground about barriers to contraception care in the aftermath of the Dobbs Decision, and reaffirm commitment to expanding access to contraception. This roundtable marked the fourth meeting in a series hosted by the [Secretary's Task Force on Reproductive Health](#).

Agile Therapeutics thanks the Administration for its continued efforts and directing the Secretaries to consider actions, to the greatest extent permitted by law, that will ensure coverage of comprehensive contraceptive care including all contraceptives approved, granted, or cleared by the Food and Drug Administration, without cost sharing for enrollees, participants, and beneficiaries.³

¹ Staff Analysis: Revised Federal Guidance Regarding Contraceptive Coverage Could Benefit Millions of Women. December 8, 2023 [House Committee Contraceptive Guidance Staff Analysis December 2023](#)

² Staff report House Committee on Oversight and Reform, October 22, 2022, [House Oversight and Reform Report October 2022 Barriers to Contraception](#)

³ President Biden Executive Order June 23, 2023 [Executive-order-on-strengthening-access-to-affordable-high-quality-contraception-and-family-planning-services June 23, 2023](#)

⁴ Sanders B, Welch P, Balint B, November 16, 2023 [Delegation letter on VT Contraceptive investigation](#)

⁵ Readout of White House Meeting on Increasing Contraception Access and Affordability, October 27, 2023, [Readout White House Report October on Contraceptive Access October 27 2023](#).

⁶ Readout of HHS Secretary Becerra's Roundtable on Contraception Access, November 8, 2023 [Readout HHS Roundtable on Contraception November 8 2023](#)

About Agile Therapeutics, Inc.

Agile Therapeutics is a women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our product and product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method. Our initial product, Twirla®, (levonorgestrel and ethinyl estradiol), a transdermal system, is a non-daily prescription contraceptive. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to allow drug delivery through the skin. For more information, please visit the company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company's website, Twitter account ([@agilether](#)), and [LinkedIn](#) account.

About Twirla®

Twirla (levonorgestrel and ethinyl estradiol) transdermal system is a once-weekly combined hormonal contraceptive (CHC) patch that contains the active ingredients levonorgestrel (LNG), a type of progestin, and ethinyl estradiol (EE), a type of estrogen. Twirla is indicated for use as a method of contraception by women of reproductive potential with a body mass index (BMI) < 30 kg/m² for whom a combined hormonal contraceptive is appropriate. Healthcare providers (HCPs) are encouraged to consider Twirla's reduced efficacy in women with a BMI ≥ 25 to <30 kg/m² before prescribing. Twirla is contraindicated in women with a BMI ≥ 30 kg/m². Twirla is also contraindicated in women over 35 years old who smoke. Cigarette smoking increases the risk of serious cardiovascular events from CHC use. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch.

Forward-Looking Statements

Certain information contained in this press release includes “forward-looking statements”, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We may, in some cases use terms such as “predicts,” “believes,” “potential,” “continue,” “anticipates,” “estimates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “likely,” “will,” “should” or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties, including statements regarding potential impact of and response to the recent report by the House Committee on Oversight and Accountability including, but not limited to the potential increase in access to no cost contraception. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. These forward-looking statements are subject to risks and uncertainties including risks related to the likelihood that the Tri-Agencies will issue revised guidance regarding ACA implementation, the response of commercial payors to any revised guidance that is ultimately issued, our ability to successfully enhance the commercialization of and increase the uptake for Twirla, the size and growth of the markets for Twirla and our ability to serve those markets our strategy, business plans and focus, and the other risks set forth in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

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