



COMMONWEALTH OF PENNSYLVANIA
OFFICE OF ATTORNEY GENERAL

MICHELLE A. HENRY
ATTORNEY GENERAL

May 24, 2024

SENT VIA UPS MAIL

Madison Campbell, CEO
Leda Health Corporation
3803 Butler Street
Pittsburgh, PA 15201

Re: Cease-and-Desist Notification to Leda Health Corporation

Dear Ms. Campbell,

The Pennsylvania Office of Attorney General (“OAG”) is hereby notifying Leda Health Corporation, its affiliates and principals (collectively, “Leda Health”), that it should immediately cease and desist advertising, marketing, and sales of products and services relating to its “Early Evidence Kits,” to consumers on the basis that Leda Health’s business practices related to the Early Evidence Kits violate the Pennsylvania Unfair Trade Practices and Consumer Protection Law (“UTPCPL”).¹

The Pennsylvania UTPCPL prohibits any person² from engaging in unfair or deceptive acts or practices in the conduct of any trade or commerce.³ The Attorney General is empowered to bring an action in the name of the Commonwealth, when acting in the public interest, to enjoin an act or practice when there is reason to believe that any person is using or is about to use any method, act or practice prohibited by the UTPCPL.⁴ The UTPCPL additionally authorizes the Commonwealth to bring an action seeking, among other relief, the imposition of civil penalties.⁵

On its website, Leda Health advertises that its mission is to change “the landscape of sexual assault prevention, care and healing.” Leda Health markets its products and services to, “hospitals, organizations, legislators and universities,” to provide, “self-administered DNA collection, and sexual health testing to meet the needs of sexual assault survivors.” The self-

¹ 73 P.S. § 201-1, *et seq.*

² The term “person” encompasses natural persons and corporations, among other meanings, 73 P.S. § 201-2.

³ 73 P.S. § 201-3.

⁴ 73 P.S. § 201-4.

⁵ 73 P.S. § 201-8.

administered DNA collection is performed using Leda Health’s product, the “Early Evidence Kit” which is featured in a video on its website,⁶ and also advertised in a video on the Leda Health *You Tube* channel.⁷ The video on the Leda Health *You Tube* channel shows the contents of the kit, which consists of a box containing an instruction manual, an intake form, a resource card, tamper-evident tape, boxes of swabs for collecting DNA from the survivor, and DNA relating to the assault, a garment bag, a storage bag and a bag with a pre-paid shipping label. Leda Health notes in the *You Tube* channel video that survivors can also connect to its mobile app, which allows the user to time stamp the collection process, capture photos and videos, and chat live with care team members, who are trained in virtual forensics collection, and available to testify in court on behalf of users. The video explains further that Leda Health also provides access to emergency contraception and sexually transmitted infection testing.⁸ Leda Health advertises that its Early Evidence Kit is for survivors, “who never make it to a hospital or care center,” and that it, “helps survivors identify where DNA may be present and collect time sensitive samples for storage or testing.”⁹

As explained on the OAG website, the Commonwealth of Pennsylvania protects the rights of survivors of sexual assault. These rights include the right to a forensic exam, the right to collection and testing of crime evidence, anonymously if desired, and the right to receive resources, including confidential support from a rape crisis center, all with no financial charge to the survivor.¹⁰

The Pennsylvania Sexual Assault Testing and Evidence Collection Act,¹¹ requires that sexual assault survivors receive evidence collection relating to their assault at no cost to the survivors.¹² The Pennsylvania Sexual Assault Testing and Evidence Collection Act further requires that the Department of Health, “test and approve commercially available rape kits for use in this Commonwealth.”¹³ The Department of Health is also charged with establishing guidelines for laboratories to receive sexual assault evidence for analysis and testing.¹⁴ Laboratories that have been approved by the Federal Bureau of Investigation to access CODIS or an equivalent federally administrated national DNA database are automatically approved.¹⁵ The Sexual Assault Testing and Evidence Collection Act recognizes the Commonwealth’s strong interest in, “the correct use and application of rape kits to maximize the health and safety of the victim and the potential to collect useful admissible evidence to prosecute persons accused of sexual assault.”¹⁶

⁶ <https://www.leda.co>, “Early Evidence Kit” video.

⁷ Leda Health channel, *You Tube*, https://www.youtube.com/channel/UC-BAgE38wU_ZfjHJlePRSnA.

⁸ “Unboxing Leda’s Early Evidence Kit,” Leda Health Channel, *You Tube*, https://www.youtube.com/channel/UC-BAgE38wU_ZfjHJlePRSnA.

⁹ <https://www.leda.co>, “Early Evidence Kit” video.

¹⁰ Pennsylvania Office of Attorney General, “Sexual Assault Victim Rights and Evidence Notification Protocol.” <https://www.attorneygeneral.gov/victim.-notification/>.

¹¹ 35 P.S. §§ 10172.1-10172.4.

¹² 35 P.S. § 10172.5(4).

¹³ 35 P.S. § 10172.3(2).

¹⁴ 35 P.S. § 10172.3(5).

¹⁵ *Ibid.*

¹⁶ 35 P.S. § 10172.3(4).

Pennsylvania law requires that sexual assault evidence collection or rape kits meet minimum standards set out in the *Pennsylvania Bulletin*.¹⁷ The standards contained in the *Pennsylvania Bulletin* include a 10-step process for collection of evidence, which requires the completion of a transfer of evidence/change of custody form. Local law enforcement agencies must take possession of the evidence collected within 72 hours of being notified of its existence.¹⁸

The Commonwealth also requires that sexual assault survivors receive treatment that meets minimum standards for sexual assault emergency services, including:

- Medical examinations and laboratory or diagnostic tests required to ensure the health, safety and welfare of the victim, or which may be used as evidence in a criminal proceeding against a person accused of the sexual assault, or both.
- Oral and written information concerning the possibility of a sexually transmitted disease and pregnancy resulting from the sexual assault.
- Oral and written information concerning accepted medical procedures, medication and possible contraindications of the medication available for the prevention or treatment of infection or disease resulting from the sexual assault.
- Medication as deemed appropriate by the attending physician, including HIV and sexually transmitted disease prophylaxis.
- Tests and examinations as medically indicated to determine the presence or absence of a sexually transmitted disease.
- Oral and written instructions advising of the need for additional blood tests at time periods after the sexual assault as medically indicated to determine the presence or absence of a sexually transmitted disease.
- Information on the availability of a rape crisis center or sexual assault counselor and the telephone number of a local rape crisis center or sexual assault counselor. The hospital shall promptly contact the local rape crisis center or sexual assault counselor at the request of the victim.
- The opportunity for the victim to consult with the rape crisis center or sexual assault counselor in person and in private while at the hospital; and
- Emergency contraception.¹⁹

A review by the OAG's Health Care Section ("HCS") has revealed that Leda Health's products and services relating to its Early Evidence Kits are not in compliance with provisions of the Pennsylvania Sexual Assault Testing and Evidence Collection Act and the UTPCPL. The UTPCPL declares as unlawful a number of practices defined as "unfair or deceptive acts or practices." These practices include but are not limited to:

- a) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services;²⁰

¹⁷ 28 P.S. 117.52 (a)(1). These standards are revised every three years. The current standards are set out in 53 Pa. B. 6784 (October 28, 2023).

¹⁸ 35 P.S. § 10172.3(c).

¹⁹ 28 P.S. §§ 117.52(a)(2)-(9).

²⁰ 73 P.S. § 201-2(4)(ii).

- b) Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by, another;²¹
- c) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connect that he does not have;²² and
- d) Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.²³

The OAG's review found that Leda Health violates the above provisions of the UTPCPL. Specifically, Leda Health:

- a) Misleads Pennsylvanians by marketing and offering for sale "Early Evidence Kits" which do not meet the Pennsylvania Sexual Assault Evidence Kit minimum requirements. As a result, a survivor using Early Evidence Kit sold by Leda Health would receive a less comprehensive collection of evidence than is available at no cost at Pennsylvania hospitals required to meet the Sexual Assault Evidence Kit requirements. The Leda Health Early Evidence Kits do not contain all elements of the kit mandated by the Commonwealth, have not been tested and approved by the Pennsylvania Department of Health, do not establish chain of custody and are not required to be taken into law enforcement possession within 72 hours. Leda Health does not make clear to consumers that the Early Evidence Kit does not meet Pennsylvania Sexual Assault Evidence Kit requirements or that it has not been approved by the Pennsylvania Department of Health for use in the Commonwealth.
- b) Misleads Pennsylvanians by marketing and offering for sale, "Early **Evidence Kits**" (emphasis added) which have not been found admissible by Pennsylvania courts, and are unlikely to be found admissible due to their insufficiency under the Pennsylvania Sexual Assault Kit requirements. Leda Health's disclaimer that it, "cannot guarantee that information collected through [its] Early Evidence Collection Kit will be offered, admitted or relied upon in a court of law,"²⁴ does not adequately inform consumers that the Early Evidence Kits do not meet the minimum standards for sexual assault evidence collection in Pennsylvania, or that they have not been approved as rape kits by the Pennsylvania Department of Health, and are unlikely to be found admissible by any court. The laboratory utilized by Leda Health does not have access to CODIS, and therefore is not among the laboratories automatically approved to receive sexual assault evidence kits in Pennsylvania. In using the term, "Evidence Kit" Leda Health is creating a likelihood of misunderstanding that the DNA collection kit meets minimum standards and may be admissible as evidence in a court. The disclaimer that Leda Health does not

²¹ 73 P.S. § 201-2(4)(iii).

²² 73 P.S. § 201-2(4)(v).

²³ 73 P.S. § 201-2(4)(xxi).

²⁴ www.leda.co/agreements

“guarantee” admissibility does not sufficiently inform consumers that the Early Evidence Kits have never been admitted by a court as evidence in a sexual assault case.

- c) Misleads Pennsylvanians by failing to disclose that the Early Evidence Kits and other Leda Health services do not meet standards under Pennsylvania’s sexual assault evidence collection laws, and Pennsylvania’s standards for sexual assault emergency services. Leda Health’s services do not include many of the services that must be provided to sexual assault survivors by hospitals in Pennsylvania, including: medical examinations and laboratory or diagnostic tests required to ensure the health, safety and welfare of the victim; medication, as deemed appropriate by the attending physician, including HIV and sexually transmitted disease prophylaxis; and the opportunity for the victim to consult with the rape crisis center or sexual assault counselor in person and in private at the hospital. Although Leda Health may offer some of the required services, including access to emergency contraception, testing for some sexually transmitted diseases, and access to a care team, these items still do not meet the requirements of the Pennsylvania sexual assault emergency services statute. Leda Health’s use of the term Early Evidence without clearly stating that its services do not meet the requirements as evidence at all, may cause confusion in survivors, who may forego the comprehensive services available at a hospital in favor of Leda Health’s services.
- d) Misleads Pennsylvanians by presenting its Early Evidence Kit, App and related services as sexual assault evidence collection, testing, and treatment services for survivors who are unable or do not want to go to a hospital, without adequately disclosing that the Early Evidence Kits do not meet the Pennsylvania sexual assault evidence collection standards and have not been found admissible by a court, or that the services provided do not meet Pennsylvania sexual assault emergency standards. This could result in survivors relying on Leda Health’s Early Evidence Kit rather than seeking care at a hospital, which could deprive them of access to vital treatment and services that are important for their mental and physical health. This could also deny survivors of access to courts and avenues to justice.

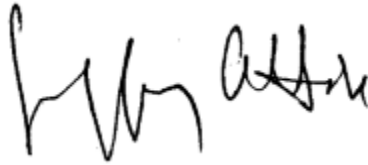
Due to the above-detailed violations of the UTPCPL, Leda Health should immediately cease and desist all advertising, marketing, and sales of products and services relating to its Early Evidence Kits. This applies to Leda Health’s marketing, sale and distribution of Early Evidence Kits to consumers, both to organizations and to individuals, and services relating to the Early Evidence Kits, including laboratory testing and live support for the Early Evidence Kits between Leda’s Care Team and consumers.

In addition to this cease-and-desist letter, the OAG will serve Leda Health with a subpoena within 14 days, directing Leda Health to provide information and documentation relating to its business practices in the Commonwealth of Pennsylvania.

In the meantime, please contact Chief Deputy Attorney General, Geoffrey Hale, of the OAG HCS at 717-574-4791 or ghale@attorneygeneral.gov within seven (7) days of your receipt of this letter to confirm that you have ceased all advertising, marketing, and sales relating to Leda Health’s Early Evidence Kits.

The failure of Leda Health to comply with this demand may result in further action by the Pennsylvania Office of Attorney General. Such action may include a lawsuit seeking injunctive relief, civil penalties, restitution, and other remedies provided for under Commonwealth of Pennsylvania law.

Sincerely,

A handwritten signature in black ink, appearing to read "Geoffrey Hale". The signature is written in a cursive style with a large initial "G" and "H".

Geoffrey Hale
Chief Deputy Attorney General
Health Care Section.