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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Joseph J. Simons, Chairman**
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter
Christine S. Wilson

In the Matter of	)	
EmpiriStat, Inc.	)	**DOCKET NO. C-4701**
a corporation.	)	

COMPLAINT

The Federal Trade Commission ("FTC"), having reason to believe that EmpiriStat, Inc., a corporation, has violated the Federal Trade Commission Act ("FTC Act"), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent EmpiriStat, Inc. is a Delaware corporation with its principal office or place of business at 327 East Ridgeville Boulevard #122, Mount Airy, MD 21771.

2. Respondent provides statistical analysis and clinical trial support services.

3. The acts and practices of Respondent as alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act.

4. Respondent has set forth on its website, http://www.empiristat.com/uploads/files/EU_US-Privacy-Shield-Policy_Dec2016.pdf, privacy policies and statements about its practices, including statements related to its participation in the EU-U.S. Privacy Shield framework agreed upon by the U.S. government and the European Commission.

Privacy Shield

5. The EU-U.S. Privacy Shield framework ("Privacy Shield") was designed by the U.S. Department of Commerce ("Commerce") and the European Commission to provide a mechanism for U.S. companies to transfer personal data outside of the EU that is consistent with the requirements of the European Union Directive on Data Protection. Enacted in 1995, the Directive sets forth EU requirements for privacy and the protection of personal data. Among other things, it requires EU Member States to implement legislation that prohibits the transfer of personal data outside the EU, with exceptions,

unless the European Commission has made a determination that the recipient jurisdiction's laws ensure the protection of such personal data. This determination is referred to commonly as meeting the EU's "adequacy" standard.

6. To satisfy the EU adequacy standard for certain commercial transfers, Commerce and the European Commission negotiated the EU-U.S. Privacy Shield framework, which went into effect in July 2016. The EU-U.S. Privacy Shield framework allows companies to transfer personal data lawfully from the EU to the United States. To join the EU-U.S. Privacy Shield framework, a company must self-certify to Commerce that it complies with the Privacy Shield Principles and related requirements that have been deemed to meet the EU's adequacy standard. Any company that voluntarily withdraws or lets its self-certification lapse must take steps to affirm to Commerce that it is continuing to protect the personal information it received while it participated in the program.

7. Companies under the jurisdiction of the FTC, as well as the U.S. Department of Transportation, are eligible to join the EU-U.S. Privacy Shield framework. A company under the FTC's jurisdiction that claims it has self-certified to the Privacy Shield Principles, but failed to self-certify to Commerce, or failed to comply with the Privacy Shield Principles, may be subject to an enforcement action based on the FTC's deception authority under Section 5 of the FTC Act.

8. Commerce maintains a public website, https://www.privacyshield.gov/welcome, where it posts the names of companies that have self-certified to the EU-U.S. Privacy Shield framework. The listing of companies, https://www.privacyshield.gov/list, indicates whether the company's self-certification is current.

9. Respondent has disseminated or caused to be disseminated privacy policies and statements on the http://www.empiristat.com/uploads/files/EU_US-Privacy-Shield-Policy_Dec2016.pdf website, including, but not limited to, the following statements:

> **EU-U.S. Privacy Policy**
> EmpiriStat, Inc. ("EmpiriStat") complies with the EU-U.S. Privacy Shield Framework as set forth by the U.S. Department of Commerce regarding the collection, use, and retention of personal information transferred from the European Union to the United States. EmpiriStat has certified to the Department of Commerce that it adheres to the Privacy Shield Principles. If there is any conflict between the terms in this privacy policy and the Privacy Shield Principles, the Privacy Shield Principles shall govern. To learn more about the Privacy Shield program, and to view our certification, please visit https://www.privacyshield.gov/.
>
> This Privacy Shield Policy sets forth EmpiriStat, Inc.'s practices with respect to personal data it receives in the United States from the European Union in reliance on the Privacy Shield Framework. To view EmpiriStat [sic] certification, you can view the Privacy Shield List at https://www.privacyshield.gov/list.

10. Although Respondent obtained Privacy Shield certification in February 2017, that certification lapsed one year later, in 2018.

11. Respondent initiated an application for recertification to Commerce in January 2018 but did not complete the steps necessary to recertify. After working with Respondent to address deficiencies in its recertification application, Commerce warned the company to take down its claims that it participated in Privacy Shield unless and until such time as it completed the recertification process. Respondent did not do so, nor did it withdraw and affirm its commitment to protect any personal information it had acquired while in the program.

12. After allowing its certification to lapse, Respondent continued to claim, as indicated in paragraph 9, that it participated in the EU-U.S. Privacy Shield framework.

13. The Privacy Shield Principles include Supplemental Principle 7, which requires any company that participates in Privacy Shield to verify, at least once a year, through self-assessment or outside compliance review, that the assertions it makes about its Privacy Shield privacy practices are true and that those privacy practices have been implemented. The verification statement must be signed by a corporate officer or the outside reviewer and is required to be made available on request to the FTC or Department of Transportation, whoever has unfair and deceptive practices jurisdiction over the company.

14. Respondent is under the jurisdiction of the FTC. During the 2017-18 period that Respondent was certified to participate in Privacy Shield, Respondent failed to comply with the requirement to obtain, through self-assessment or outside compliance review, an attested verification statement that the assertions it had made about its Privacy Shield privacy practices during the time it participated in the program were true and that those privacy practices had been implemented. Respondent failed to provide its attested verification statement to the FTC.

Count 1-Privacy Misrepresentation

15. As described in Paragraph 9, Respondent represents, directly or indirectly, expressly or by implication, that it is a current participant in the EU-U.S Privacy Shield framework.

16. In fact, as described in Paragraphs 10-12, Respondent is not a current participant in the EU-U.S. Privacy Shield framework. Respondent's certification lapsed in 2018, and it was not renewed. Therefore, the representation set forth in Paragraph 15 is false or misleading.

Count 2-Misrepresentation Regarding Verification

17. As described in Paragraph 9, Respondent represented that it complied with the EU-U.S. Privacy Shield framework principles.

18. In fact, as described in Paragraphs 13-14, Respondent did not comply with the EU-U.S. Privacy Shield framework principles. In particular, it failed to comply with the verification requirement in Privacy Shield Supplemental Principle 7. Therefore, the representation set forth in Paragraph 17 is false or misleading.

Count 3-Misrepresentation Regarding Continuing Obligations

19. As described in Paragraph 9, Respondent represented that it complied with the EU-U.S. Privacy Shield framework principles. These principles include a requirement that if it ceased to participate in the EU-U.S. Privacy Shield framework, it must affirm to Commerce that it will continue to apply the principles to personal information that it received during the time it participated in the program.

20. In fact, as described in Paragraph 11, Respondent has not affirmed to Commerce that it will continue to apply the principles to personal information that it received during the time it participated in the program. Therefore, the representation set forth in Paragraph 19 is false or misleading.

Violations of Section 5 of the FTC Act

21. The acts and practices of Respondent as alleged in this complaint constitute deceptive acts or practices, in or affecting commerce, in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this thirteenth day of January 2020, has issued this complaint against Respondent.

By the Commission.

April J. Tabor
Acting Secretary

SEAL
ISSUED: January 13, 2020