

Case Study Handout

Elberg Healthcare, LLC requested an EUA (Emergency Use Authorization) pursuant to Section 564 of the federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 360bbb-3) for its COVID-19 test kit, “The Elberg 1000 SuperKit.” The FDA granted Elberg’s request in a letter of authorization dated February 1, 2021. In that letter, FDA authorized the intended use of The Elberg 1000 SuperKit as follows:

“Intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is for prescription home use with self-collected nasal swab specimens in individuals aged 14 and older who are suspected of COVID-19 by their healthcare provider.

This test is also authorized for use at the point of care (POC), in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, with self-collected nasal swab specimens in individuals aged 14 and older, and in individuals aged 13 and under when the specimen is collected by a healthcare provider at the POC.

This test utilizes a molecular amplification technology for the detection of SARS-CoV-2 RNA in individuals with known or suspected COVID-19.”

This authorization for The Elberg 1000 SuperKit represents the only COVID-19 test kit EUA that Elberg Healthcare, LLC has sought and received from FDA. Shortly after receiving the FDA authorization, Elberg Healthcare, LLC created a website, elberg1000superkit.com, via which the company offers three COVID-19 test kits, including The Elberg 100 SuperKit for sale to consumers. The Elberg 1000 SuperKit webpage further states: *“The U.S. Food and Drug Administration has approved The Elberg 1000 SuperKit to mitigate, prevent, treat, diagnose, and cure COVID-19.”*

Questions:

What concerns do you have about Elberg Healthcare, LLC’s marketing of its various COVID-19 test kits to consumers on its website?

What concerns do you have about Elberg Healthcare, LLC’s Elberg 1000 SuperKit website?

As part of its marketing program, Elberg Healthcare, LLC has engaged Dr. Tara Talker to give educational talks to audiences of practitioners about her experience with The Elberg 1000 SuperKit. Dr. Talker refers more of her patients for testing using The Elberg 1000 SuperKit than any other doctor. Elberg Healthcare pays Dr. Talker \$1,000 for each presentation she gives. Dr. Talker has been giving an average of three presentations per week since February. Due to COVID, Dr. Talker has been giving her presentations via Zoom. Dr. Talker has stated she prefers presenting over Zoom, and would like to continue presenting via Zoom even when in-person presentations are again possible.

Questions:

What concerns do you have about Dr. Talker giving paid presentations? (Put aside, for purposes of this question, any additional concerns you have based on the presentations being via Zoom.)

What concerns do you have about Dr. Talker continuing to present via Zoom? What can you do to ensure the presentations are compliant?