August 20, 2018

Federal Trade Commission Office of the Secretary Submitted electronically

I am the General Counsel and Chief Regulatory Officer of <u>Ciitizen</u>, a health technology start-up in Silicon Valley, California. We are creating a personal health record platform that will enable consumers to collect, manage, and share their comprehensive health histories, in accordance with their wishes and under their control. I am submitting these brief comments regarding the notice published in the Federal Register on Monday, August 6, 2018, regarding the Commission's intent to hold hearings on "Competition and Consumer Protection in the 21st Century." (83 Fed. Reg. 38307) (Note: Because this comment also may be relevant to question #3, I am submitting this comment there as well.)

Much of the valuable clinical information about consumers/individuals is created by hospitals, doctors, laboratories, pharmacies and other health care provider entities – but maintained by large, electronic health record (EHR) vendors. Individuals have a right under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to copies of their health information from these clinical providers, and the EHR vendors – which are HIPAA business associates – are required to make this information available.

As a personal health record vendor, we intend to make it easy – and ideally frictionless – for our individual users to collect their health information and have it at their fingertips. However, we are already experiencing challenges in accessing our users' health information, and EHR vendors are serving a significant "gating" role with respect to the clinical information they are holding on behalf of their provider customers. Specifically, some EHR vendors are imposing significant charges on other app and software vendors who are seeking access to the health information these vendors hold for their provider clients. For example, such vendors operate platforms, and app vendors must pay fees and meet other criteria in order to be accessible on this platform. For personal health record vendors like Ciitizen, we must pay EHR vendor fees in order for our consumer users to be able to seamlessly access the user's health information (and exercise their HIPAA rights), but these vendor fees also create constraints for apps seeking to provide services to health care providers. (I have not provided an example of these fees in this comment, as it may be considered to be competitively sensitive cost information.)

Although the fees may pose a significant barrier to entry, EHR vendors are also setting privacy and security criteria at their discretion. The intent of such criteria is laudable – to assure that sensitive health information is accessible only to authorized persons. However, when those privacy and security criteria are not standardized, and EHR vendors are permitted to establish their own requirements, these protective criteria can become additional barriers to entry.

Although these EHR vendors presumably answer to their health care provider clients, in many cases the vendor has greater market power to dictate the terms of the arrangement.

As is frequently the case with barriers to market entry, small vendors experience greater impact.

I urge you to include the topic of barriers to health information markets in your upcoming hearings. Although I have highlighted some concerns with respect to gating criteria imposed by EHR vendors, the practices of health care providers subject to FTC jurisdiction should also be explored.

Respectfully,

Deven McGraw General Counsel & Chief Regulatory Officer