

Senator Floyd Prozanski  
Oregon State Senator  
900 Court St. NE, S-413  
Salem, Oregon 97301

February 17, 2019

Re: Personal Testimony of T. Anthony Howell in support of Oregon Senate Bill 703

Dear Senator Prozanski,

I am a professional technologist and in 2014 co-founded rareLife solutions to build online communities to meet the special needs of people impacted by rare diseases. I am an attorney licensed in both New York and Connecticut (my current residency and headquarters of rareLife solutions). I serve as rareLife's compliance officer and am familiar with privacy issues related to HIPAA, FDA, CCPA and GDPR. Over the past two years, I have drafted three comments<sup>1</sup> to the FDA regarding the value of verifying patients' diagnoses as a foundational effort to establish credibility of patient reported data.

When developing our business plans, rareLife solutions recognized the failure of large-scale social media data collection companies to address the "data issue" – particularly with respect to the unique needs of families impacted by rare diseases.<sup>2</sup> People impacted by rare diseases (over 350,000,000 worldwide, and 1 in 10 people in the USA) have on average massive amounts of healthcare data to provide to those who are researching and manufacturing treatments and cures.

Given the rarity of patients, the value of their data is enormous. Of equal value is the inspirational commitment by those patients to the clinical research continuum which often requires multiple times a day monitoring, recording and reporting, along with arduous travel and time away from work, school and other obligations. Advancing clinical trials is a daunting process that often fails early due to lack of enrollment and high dropout rates. It is estimated that **"only 15% of clinical trials are able to retain enough patients to completion"**<sup>3</sup> and the **"average dropout rate across all clinical trials is as high as 30 percent."**<sup>4</sup> The rights of patients in clinical trials has been evolving ever since the terrors of the abusive Tuskegee Syphilis Trials<sup>5</sup> with the development of regulations, penalties and many safeguards including Institutional Review Boards. To increase clinical trial enrollment and retention enabling researcher to unlock the mysteries of rare diseases, it is now time for a similar evolution in patients' rights to have their data treated as property for which they can have options over remuneration. We believe such options would enhance research by fostering greater interest in participation in clinical trials.

In reaction to the ubiquitous social healthcare platforms that surreptitiously request its members **"donate their data for good"** and then sell access to it without notice or remuneration, our business model was designed to incorporate people from within rare disease communities for a multitude of authentic purposes. We attend and speak at many healthcare conferences and often see the vaunted rubric "patient-centric" or "patients as partners." Regrettably, this is oftentimes characterized as marketing-speak with little substance of value to the patient.<sup>6</sup> **We believe true patient-centricity is only possible if the patient family is part of the economic ecosystem; this is the new patient-centric model.**

Before we engage in survey endeavors involving community member data, we describe the project's goals to the survey participant, the potential uses for which the data is sought and may be used and the amount of money available for participation in the survey. We also remunerate our patient, advocate, caregiver, healthcare professional, and researcher members for their participation in our working groups and other opportunities that recognize their valuable input.

We are encouraged by the efforts of the technology community to bring the transparency of blockchain to personal data of all kinds and encourage the Oregon State Legislature to support the creation of property rights in personal data for its residents.

rareLife solutions respectfully requests SB 703 be passed.

Sincerely,

T. Anthony Howell, co-founder, rareLife solutions

<sup>1</sup> rareLife solutions comments regarding the importance of verifying patient diagnosis and the pitfalls of invalid data:

<https://www.regulations.gov/document?D=FDA-2017-N-5896-0005>

<https://www.regulations.gov/document?D=FDA-2018-D-1893-0035>

<https://www.regulations.gov/document?D=FDA-2018-N-2455-0049>

<sup>2</sup> The FDA Orphan Drug Designation is provided to diseases for less than 200,000 people in the US.

<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018190.htm>

<sup>3</sup> Center for Healthcare Innovation <https://www.chisite.org/blog/2018/3/28/a-patient-centered-approach-in-clinical-trials-impact-on-patient-retention-and-costs>

<sup>4</sup> StatNews <https://www.statnews.com/2018/09/21/clinical-trials-reinvention-janssen/>

<sup>5</sup> Centers for Disease Control and Prevention, <https://www.cdc.gov/tuskegee/timeline.htm>

<sup>6</sup> PharmaTimes, [http://www.pharmatimes.com/magazine/2018/may\\_2018/walking\\_the\\_patient\\_centric\\_talk](http://www.pharmatimes.com/magazine/2018/may_2018/walking_the_patient_centric_talk)