Testimony of

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Before the National Committee on Vital and Health Statistics
Subcommittee on Privacy, Confidentiality and Security

May 20, 2009

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On behalf of PatientsLikeMe and the 35,000+ patient members of our online community, I thank you for the invitation to testify before your Subcommittee regarding privacy issues related to patient-facing online services and the future landscape of healthcare.

PatientsLikeMe (www.patientslikeme.com) is a free online community for people with life-changing diseases, including ALS, Multiple Sclerosis, Parkinson's disease, HIV/AIDS, Mood Disorders, Fibromyalgia and orphan diseases (such as Devic's Neuromyelitis Optica, Progressive Supranuclear Palsy and Multiple System Atrophy). Our mission is to improve the lives of patients through new knowledge derived from their shared real-world experiences and outcomes. To do so, we give our members easy-to-use, clinically validated outcome management tools so they can share all of their disease-related medical information. Our website is also designed to foster social interaction for patients to share personal experiences and provide one another with support. The result is a patient-centered platform that improves medical care and accelerates the research process by measuring the value of treatments and interventions in the real world.

Founded in 2004 by myself, my brother Benjamin Heywood, and long-time friend Jeff Cole, PatientsLikeMe was inspired by our personal experiences with ALS; our brother and friend, Stephen Heywood, was diagnosed with this disease at the age of 29. We are a privately funded company that aggregates our members' health information to do comparative analysis and we sell that information to partners within the industry (e.g., pharmaceutical, insurance companies, medical device companies, etc.). We believe that openly sharing information provides an important pathway to accelerate research and improve medical care. This "Openness Philosophy" is at the core of who we are as a company.

alsking101
Male, 38 years
Newton, MA

ALS: 9 yrs

Diagnosis Summary
Onset: Arms
First symptom: Nov 1997
Diagnosis: Jan 1998
Deceased date: Nov 26, 2006

Updates
Last updated: Oct 15, 2006

What is Openness?

As we move forward in health information technology (HIT), it is vital that we understand the value and potential of openness. At PatientsLikeMe, our Openness Philosophy, written by colleague David S. Williams III, reads as follows:

> *Openness is a good thing.*
>
> *Most healthcare websites have a Privacy Policy. Naturally, we do too. But at PatientsLikeMe, we're more excited about our Openness Philosophy. It may sound counterintuitive, but it's what drives our groundbreaking concept.*
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> *You see, we believe sharing your healthcare experiences and outcomes is good. Why? Because when patients share real-world data, collaboration on a global scale becomes possible. New treatments become possible. Most importantly, change becomes possible. At PatientsLikeMe, we are passionate about bringing people together for a greater purpose: speeding up the pace of research and fixing a broken healthcare system.*
>
> *Currently, most healthcare data is inaccessible due to privacy regulations or proprietary tactics. As a result, research is slowed, and the development of breakthrough treatments takes decades. Patients also can't get the information they need to make important treatment decisions. But it doesn't have to be that way. When you and thousands like you share your data, you open up the healthcare system. You learn what's working for others. You improve your dialogue with your doctors. Best of all, you help bring better treatments to market in record time.*
>
> *PatientsLikeMe enables you to affect a sea change in the healthcare system. We believe that the Internet can democratize patient data and accelerate research like never before. Furthermore, we believe data belongs to you the patient to share with other patients, caregivers, physicians, researchers, pharmaceutical and medical device companies, and anyone else that can help make patients' lives better.*
>
> *Will you add to our collective knowledge... and help change the course of healthcare?*

With the value of openness comes the responsibility of transparency. While PatientsLikeMe does not fit squarely in the role of a personal health record, our platform does allow patients to record, measure and share their symptoms, treatments and outcomes with others in the community and, if so chosen, the world. Thus, it is our responsibility to be upfront about what the risks and benefits are for patients, as well as how their information will be used (i.e., sold in aggregated form to industry partners). We address all of these issues on the website. Here is an excerpt from our frequently asked questions (FAQs) addressing risk and benefits:

> *When sharing information about an illness or disease in any community, there is always a risk that someone could use this information against you. Medical and life insurance companies have clauses that exclude pre-existing conditions. Employers may not want to employ someone with a high-cost or high-risk disease. We know these risks are real.*
>
> *We also believe that openly sharing information (see our Openness Philosophy) is an important way to improve medical care. Ultimately, it is your decision to make about how to balance these risks. We do not display your name or email address and you control what information you enter and, therefore, share. The more personal information you share (e.g., photos, location, birthday or other personal information which is*

> *optional to add in your profile) on our site, the more risk there is that someone can identify you. The more information patients share, the more valuable that information is to everyone. So, all we can ask is that you participate as fully as you feel safe doing.*

What About Privacy?

In today's evolving healthcare landscape, privacy impacts the ability to create and share the type of comparative analysis done by PatientsLikeMe in two major ways: legally and philosophically.

From a legal perspective, privacy needs to effectively balance the needs of three broad groups of people, including:

- Those for whom high levels of privacy is an active and ongoing concern;
- The average person who routinely trades some privacy for value or benefit;
- Those who are open and willing to share with the community and world.

We recognize that it is difficult to legally define one set of rules that addresses these three different health consumers, while also taking into consideration all of the different environments (including government-provided healthcare, private healthcare, service-based healthcare, voluntary participation in shared care, such as PatientsLikeMe, as well as voluntary research participation). This will only get more and more difficult as personal health records and other HIT initiatives evolve over time. As we address (through our policies) the need to protect the privacy rights of those that wish to prevent the flow of their information or their personal data, we need not restrict the rights of those in our society who wish to openly share and participate in their care on a one-to-one or community basis. Additionally, we need not infringe upon the rights of those who wish to openly participate in research.

PatientsLikeMe is not for everyone, but for those people who feel comfortable openly exchanging their health data, the site can play a critical role in managing their disease. These patients also provide great benefit to the rest of the disease community through providing their information. It's the voice of those patients that helps us forge ahead with our mission.

We encourage patients to voice their opinions regarding the privacy and security issues that arise as they try new services, like ours. There are more than 650 forum discussion threads across our communities regarding the issue of privacy. One of the threads is in response to a blog posted by the Center for Democracy and Technology last October. The blog cites a survey in which "67% of respondents said they're either 'somewhat' or 'very' concerned about the privacy of their personal medical records." We asked members of our Multiple Sclerosis community to respond to this statement on our forum. Here are some of their responses:

> "I believe the benefits of participating in a health care system using online records outweigh privacy concerns. What privacy? Given the resources anyone can find out anything about my background."
>
> "That [online medical records is] inevitable is probable, but I still believe that we should have the right to say who knows what, when and if about ourselves. It's the freedom of choice, will and about human dignity!"
>
> "My medical records are open, wanna see? Just look at PLM (PatientsLikeMe)!!!"

From our experiences at PatientsLikeMe, we know patients are aware of the issues. They understand and weigh the risks and benefits, and are intelligently making rational choices about where they are comfortable sharing information and how their information will be used to help. If we infringe on this right to share or speak (in the interest of preventing discrimination), we are preventing the flow of information and, by our read, acting contrary to the values on which our country was founded.

Privacy is also more than a legal concept, it is also a philosophical concept. A modern focus on privacy as a goal, not as a right, has moved the line to the point that medicine is slowed, treatments are delayed, and patients die for failure to have what they need when they need it. We have substituted real harm for mostly theoretical harm. We would even argue that the philosophical focus on privacy is a bad thing. We believe that openness is much more powerful concept than privacy in medicine, and one that gives patients the power to take control of their health.

Idealized Medicine

In an ideal world, we would be able to personalize and measure health improvement, management of disease, and medical care. People would be supported in the issues they deal with by those most appropriate. Support with the challenging and difficult decisions we all face (such as those around health, life and, ultimately, the reality of death) would be provided by those who have the most experience and empathy to share in those situations.

How the U.S. healthcare system operates today is far from this ideal. When we begin to share and measure what matters to patients in the context of health and illness, we will start the journey to the world where a patient knows what they need to know, when they need to know it; a world where a patient has the confidence that the actions taken on his or her behalf are of high-quality and are effective.

Our ultimate goal is to allow a patient to reach that ideal. At PatientsLikeMe, the journey begins when patients can find someone like them with their symptoms, diagnosis, treatments, and life issues. This allows patients to see the quantitatively-measured benefits that can be achieved by changing lifestyles and treatment choices and developing skills; they can help themselves achieve as much as possible within the context of their impairment. To do this, we measure these elements and have begun the process of providing each individual a way to record their own personal health in the context of others like them.

This system, when fully realized, will be able to predict the future probability and impact of changes in choices. Fully realized, this system gives each patient the clear risk-benefit knowledge of their own choices, and that of others who have been through it, to support them in their decisions.

There are many components that are necessary to reach this future ideal state and it requires a transformation in ownership, reimbursement, information, as well as investment in knowledge systems and consumer education. These transformations are very difficult to achieve.

Openness and Voluntary Leadership

PatientsLikeMe, as a voluntary effort driven by the patients most committed to helping each other reach that state, is an example of an innovation that is possible when those economic, ownership, and reimbursement rules are changed. It does not and cannot provide a comprehensive health record solution, nor is it designed to meet the needs of billing, liability reduction, and operations for health systems. However, it is an idealized patient-centered health framework for the diseases in which we operate. As such, it can change how the system works today and it can also begin to show what is possible when data is openly exchanged, and collaboratively used in the interests of patients.

So what is possible? To date, more than 35,000 patients embrace openness and are sharing information about their condition on PatientsLikeMe. We recently surveyed our members to learn more about how the website is helping them. Per their responses, we know that patients find that by openly sharing information they are, at the very least, improving their quality of life and communication with healthcare providers.

- Of the 1,235 survey respondents, 62% report their "quality of life is better" as a result of using the website and 78% report "PatientsLikeMe has helped me understand my own prognosis."
- Among the respondents from our combined mood community (i.e., those with depression, bipolar, anxiety, obsessive compulsive disorder, and post-traumatic stress disorder), 25% say they "think about harming themselves less as a result of using PatientsLikeMe" and 1 in 5 (22%) feel they "needed less inpatient care as a result of using the site."
- Of the patients with HIV/AIDS who responded to the survey, the majority (62%) say they now "know about the risks and benefits of a drug holiday because of PatientsLikeMe," with 39% citing reduced "risky [sexual] behaviors" as a result of using the website.
- For our newest community, Fibromyalgia, 85% of survey respondents agree or strongly agree with the statement "I feel better about myself because of recognition by others at PatientsLikeMe that my condition is real."

We share these survey responses to provide a sense of the immediate value that can be derived for patients. Through the open exchange of data, peer learning and improved care is also possible. Here are two real-world examples:

Example: A patient in our Multiple Sclerosis community realizes he is taking too low a dosage of Baclofen, works with his doctor to increase it, and relieves his symptoms.

From our MS Forum:

Before PatientsLikeMe:

For years I had always taken just 10mg of Baclofen. I was told a long time ago by my old neuro that "too much Baclofen can cause weak legs". We'll yes, that maybe true but after 10 years, I probably should have re-inquired. whoops

Then:

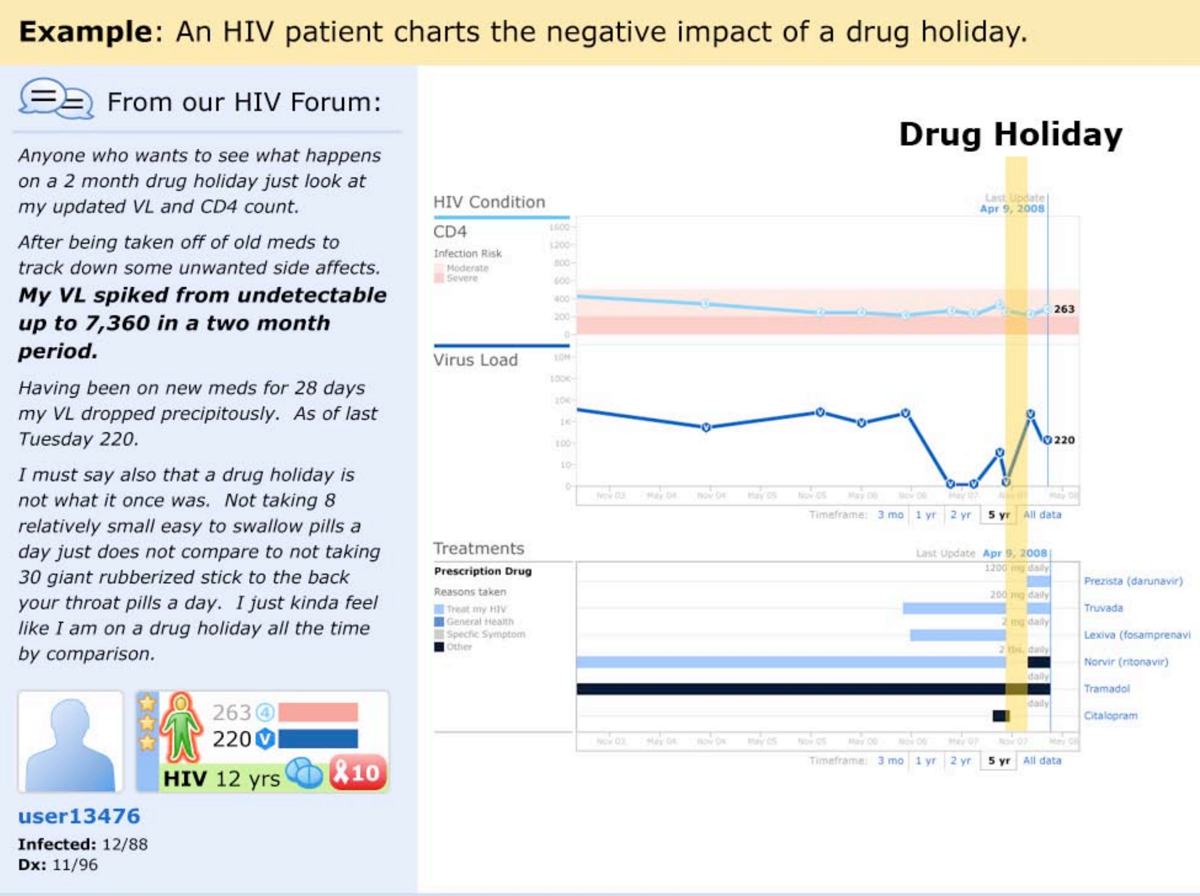
I sign up here. Take a peak at what you guys are doing, and find out I don't take enough Baclofen to deal with my symptoms. Give the neuro a call, no problem, and much, much, better.

user479
sensory changes onset: 04/93
Dx: 01/94
Type: Secondary Progressive

Top MS Symptoms
Fatigue (566 patients)
Stiffness/spasticity (520 patients)
Pain (461 patients)
Excessive daytime sleepiness (450 patients)
Brain Fog (440 patients)
Mood Swings (424 patients)
Anxiety (414 patients)
Depression (412 patients)
Bladder Problems (399 patients)
Sexual dysfunction (347 patients)
See all 140 symptoms...

Stiffness/spasticity
Muscle spasticity is characterized by tight, stiff muscles and is a common symptom of several neurological disease, causing cramping, stiffness, and muscle discomfort. Read more...

What we've learned



Example: An HIV patient charts the negative impact of a drug holiday.

From our HIV Forum:

Anyone who wants to see what happens on a 2 month drug holiday just look at my updated VL and CD4 count.

After being taken off of old meds to track down some unwanted side affects. ***My VL spiked from undetectable up to 7,360 in a two month period.***

Having been on new meds for 28 days my VL dropped precipitously. As of last Tuesday 220.

I must say also that a drug holiday is not what it once was. Not taking 8 relatively small easy to swallow pills a day just does not compare to not taking 30 giant rubberized stick to the back your throat pills a day. I just kinda feel like I am on a drug holiday all the time by comparison.

user13476

Infected: 12/88

Dx: 11/96

The possibilities extend far beyond these individual insights as well. The potential for accelerating research and understanding real-world products is very promising under the umbrella of openness. Here are three examples:

- **Does Lithium Work for ALS Patients?**
  On February 12, 2008, Proceedings of the National Academy of Sciences (one of the leading science journals) published a paper entitled — "Lithium Delays Progression of Amyotrophic Lateral Sclerosis." At that time, PatientsLikeMe had data on the progression and condition history of more than 2,000 ALS patients - twice the number in the largest ALS trial in history. Over the course of 2008, more than 400 patients worldwide elected to start taking lithium, in collaboration with their doctors, and charted their progression and blood levels on PatientsLikeMe. This is more than twenty times the number of patients who participated in the trial itself. (Data analysis is still under way, but the evidence indicates that lithium is not as effective as suggested by the PNAS study.)

- **Potential Mechanism of Excessive Yawning in ALS:**
  In 2007, a paper about excessive yawning in two patients on SSRIs prompted a discussion on the PatientsLikeMe forum. As more and more patients confirmed experiencing this symptom, PatientsLikeMe added "excessive yawning" as a primary symptom in ALS. Within two weeks, data from 254 ALS patients showed excessive yawning was twice as common in patients with bulbar onset of symptoms. PatientsLikeMe's study found that painful, uncontrollable "excessive yawning" was relatively common in the bulbar-onset form of ALS, and findings were published in the journal Acta Psychiatrica Scandinavica in 2007.

- **Pathological Gambling Amongst Parkinson's Disease Patients**
  In a recently published study by PatientsLikeMe, we found a higher level of problem gambling in our PD population (as defined by the South Oaks Gambling Scale) than previous studies; 13% of PD patients as opposed to previous estimates of around 4% (or Mayo Clinic's recent estimate of 2.6% which included hypersexuality).

As we use this real-world patient data for research purposes, we are often questioned about its validity. Do we believe the data shared through our site, or via personal health records, will be a "source record" for medical information? The reality is that all information in health is compromised by biases and errors. This is true of even standard tests and diagnostics. For something to be a source record, you must be able to trace back to its origin (e.g., What lab? What question? What procedure? What were the variables and who signed off on the data?). These are simple problems to solve in any accounting system and it is disappointing that healthcare has lagged so far behind in adopting and understating the value of knowing this simple information trail.

The source of the data though is not as important as what the data means in the context of the patient. Diagnostic lab and physician options do have value, but need to exist in the patients' health framework. The patient's perception of health should drive any health system and diagnostics must be interpreted in the context the patient's health perception. A patient's health is not reflected in a blood test, it's reflected in his or her ability to work, love and be part of society.

Health, Costs and Engagement

Electronic health records (EHRs) and personal health records (PHRs) serve many masters: the doctors, hospitals, insurance companies, supply management, risk management programs, and most of all the transactional-based economy of healthcare. They contain little valuable health information, and almost none of it is in a computable form, where it might be possible to use that information to help the patient make better decisions. If EHRs and PHRs are to serve either health or cost goals, they must contain useable computable information on both health outcomes and cost. This evolution will ultimately lead them to see the definition of health and cost in patient-centered terms.

We believe that the applications like PatientsLikeMe, which can help patients manage their health and conditions, need to be in the control of the patient. These applications will need to be served by the medical system with accurate high-quality data on the diagnosis, results of tests, and interventions of the medical system. Because patients will be responsible for the operation of their health application, they will define the standards that the medical system will need to meet to help the patients achieve their optimal health outcomes in the context of their disease. Patients should be empowered to require that the data meet quality and information exchange standards in order for the service to be reimbursed.

Initially, we believe those with the greatest information needs will be those with ambiguous illnesses with ambiguous treatment options and where their health is having the largest life impact. Uptake from an information management standpoint will be highest from a patient perspective in those areas. As information tools improve over time, they will provide better health outcomes, more informed decisions and reduce uncertainty. This will expand engagement to more patients. In the end, adoption is a return on investment decisions – people invest their time only where it delivers value as they see it.

The Future is Open

We ask that the vision we describe throughout this statement, and the value that can be created by the free speech expressed in our voluntary citizenship participation efforts, not be infringed. The future of healthcare hinges on allowing people to benefit from the value of openness.

> *We envision a world where information exchange between patients, doctors, pharmaceutical companies, researchers and the healthcare industry can be free and open; where, in doing so, people do not have to fear discrimination, stigmatization or regulation; and where the free flow of information helps everyone. We envision a future where every patient benefits from the collective experience of all, and where risk and reward of each possible therapeutic choice is transparent and known.*
>
> *- PatientsLikeMe.com FAQ*

At an accelerating pace, more and more information regarding our purchasing behavior, our health, our finances, our travels, and our work will be linked through computers systems that can connect everything that is unknown about us. Information that is not explicitly recorded can nevertheless be inferred by statistical association, and sufficient information reveals all. One does not need a health record to recognize patterns of depression. Our Internet searches reveals much more about us than the most comprehensive health record. Our credit cards reveal more about our health than our hospital record. As this information is increasingly used to market, profile and make decisions about our life insurance, employment, and even legal issues, we will need to rethink the privacy and discrimination issues. When cell phones have GPS, and the pictures we take are tagged by our location, privacy will take on a new meaning.

We have to begin to work on building a society that allows the variation in human health and the variation in human condition, one that allows people to be philosophically created equal. We need to work on building a society where information is not used to discriminate, but to assist and support and improve. Restricting the flow of information will not advance solving this problem.

This is not a simple transformation, but we believe it is inevitable. The major privacy issues are not only about health records, but the invisible trail of "breadcrumbs" we leave behind us day to day in life. Health is not a separate concept. It is an integrated concept and, in an integrated world, we have to decide how to build a society that can handle the reality that not all are healthy. We need to work together to get the most productivity and life from all of us.

We believe openness can lead the way to such a society.

On behalf of PatientsLikeMe and those we serve, I thank you once again for inviting me to testify before you regarding these very important issues.