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An Account of the Development of H.R. 6498:  
Genomics and Personalized Medicine Act of 2008

With great excitement and anticipation, I began my internship in the office of Congressman Patrick Kennedy of Rhode Island's office on the morning of June 2<sup>nd</sup>. A small office with four Legislative Assistants, two Staff Assistants, a Legislative Fellow, Scheduler, Appropriations Staffer, and Chief of Staff, the office seemed to be built in a way that kept interns out of sight and mind. In our small corner, remedial tasks were assigned and minimal involvement was encouraged. By my third week, having had enough with the low expectations and simplistic chores and errands, I spoke with my advisor in regards to being assigned some other kind of work or higher-level thinking task.

Mrs. Alford, my advisor and, as the summer progressed, a great friend, then handed me off to the office's Legislative Fellow, an energetic and jovial older woman named Christina Moore. Having been sponsored by Doctors Without Borders, of which she had been a part of for more than twenty years, Dr. Moore had come to Washington to work on a specific bill in her specific fields of neurology, psychology and personalized medicine.

The bill, as I would come to learn, was a complicated and structurally untested formula for dealing with the new-age problems of genetic testing. Having had no medical teaching or interest for science, Dr. Moore put me through an intense training course of written materials and website articles that, over time, gave me a stronger grasp of, not only genetic testing, but the entire industry of online and personalized medicine and the prospects for its success.

Genetic testing is a topic of study that originated after the human genome had first been mapped in 2003 by Dr. Watson of the Human Genome Project. What followed was a rush of research and media attention focusing on the possibilities and pitfalls of this new form of medicine, a form of medicine that could look at an individual's genes and find their entire lives spelled out in the 25,000 separate variables. As the media reported the findings of the HGP, the ability for doctors to observe an individual's genetic information would allow for medicine to be more wisely prescribed, threats of cancers and diseases more soundly addressed, and the chance for negative reaction to outside stimuli predicted.

This media feeding frenzy over the issue of genetic testing is one of the reasons Congressman Kennedy chose to become involved in the testing market. Companies like 23andme.com and Navigenics.com had taken the step to advertise themselves directly to consumers, avoiding the involvement of doctors in getting to the patient. These companies, after performing the tests (a simple measure of sending in a cotton swab wiped inside the mouth and a check for no less than a thousand dollars) would then advise the consumer that while often very accurate, the tests could not be used as solid fact when dealing with a legitimate health concern. The test would, for example, show an individual her familial chance of heart disease, but this information should only be used to provide guidance in what routes of further study, through a doctor and laboratory, she should follow.

And herein lies the larger enigma. When a doctor has no control over which test a consumer utilizes, but is then approached by the consumer with fears and apprehensions in how they are treated medically, can the doctor trust the tests he is being presented with?

Congressman Kennedy's bill seeks to fix some of the problems in the up-to-now unregulated market of genetic tests and their equivalents. The legislation combines two pieces of legislation that had already been submitted by Senator Ted Kennedy of Massachusetts and Senator Barack Obama of Illinois the year before on the opposite side of the Congress. Senator Kennedy's legislation dealt with a genetic testing database that would allow for any doctors or medical researchers to see what tests are available, regardless of their market availability, giving a better picture, for the industry, of where the tests are headed and what researchers should still be looking into. One key feature that Congressman Kennedy's legislation performs is the requirement that any test that is in its beginning stages, no matter its estimated efficacy and accuracy, must be registered in the database. This allows for an overarching perspective on whether a certain test works, promoting a better follow-through on the applications and qualities of the tests. Senator Obama's legislation was more of a privacy issue. It dealt with what to do with the DNA samples the companies that provide genetic tests take in. While major laboratories at Duke University or Brown University (which is in the Congressman's district, establishing another key interest in the issue) have official biobanks in which they store and save the samples they have, many other institutions lack such capabilities. It is for these groups that, with the Genetic Information Nondiscrimination Act of 2008, extreme caution must be taken.

What followed was an intense and demanding list of meetings to attend with Dr. Moore and conferences to be present at in her stead. I attended forums hosted by the Food and Drug Law Institute, the American Association for the Advancement of Science, the

Department of Health and Human Services, the American Clinical Laboratory Association, the National Institute on Drug Abuse, and the Centers for Medicare and Medicaid.

As these meetings went on, Dr. Moore gave me a wide perspective on the kinds of power plays and associations required to get the legislation passed. Dr. Moore worried that, after her fellowship ended, the bill would be sent to more committees than had been anticipated, and it was her intention to limit it to no more than four that she felt rightly deserved a part in the bill's final analysis and approval. These committees are Labor and Education, Science and Technology, Ways and Means, and Energy and Commerce.

Dr. Moore took the time to find which Congressmen and women would need to be addressed to cosponsor the bill. She first attained the lists of the members of each of the committees she was hoping to send the bill to. From there, she then narrowed down her lists to those Congressmen who were doctors or had the fortune of presiding over a district that housed a major medical community or institution.

The final process of "purification" of the bill was a repetitive series of phone conversations with doctors and experts on legislative language in order to clarify the issues of money, topic placements in the bill, and, most surprisingly, definitions. One definition in particular, pharmacogenetic test, caused a whole host of problems in defining in a concise manner. A complicated term, Dr. Moore and the Congressman worried it could stretch to include, not only the genetic tests targeted, but a whole bevy of genotype characteristics.

And finally, on July 15, 2008, Dr. Moore went to the office of the Congressional Secretary to drop off the finalized copy of the bill.

As Dr. Moore returned to the office, she and I went to lunch to celebrate. Upon our return to the office, she returned to her email and began preparing the next bill for the next fellow to come in to the Congressman's office.

The unpredictable ebb and flow of the office was difficult to get a hold of, especially in an office that's main issue of concern was 21<sup>st</sup> century medicine, for from any of my own interests. Fortunately, with Dr. Moore's training and guidance, my perspective on the process of taking an idea and putting it into the form of concise and effective legislation grew exponentially, and with House Resolution 6498 in my past, I feel more confident and secure in my idea of what Congress's role is and what it must do to achieve its goals.