



The Early/Expanded Access Program for Prostate Cancer Patients

July 15, 2011

Dear Friends,

Finding a common nexus or belief among each other is not always easy, even when it comes to such critical and profound things such as cancer screening and certain types of cancer treatment. It is very easy to find individuals passionate on either side of the argument.

Yet, other items or subjects appear almost unequivocal and finding a consensus takes no time, and I believe this is a starting point for what can unite us to do great things for people. For example, catastrophic care of patients, or in other words, the belief that no one person or family should lose everything financially they have worked for in life because they get sick, which is not an easy problem to solve overnight compared to my next example.

I believe we would primarily agree that individuals have a right to access a promising drug (and/or drug coverage information) if they are or have run out of options, despite that drug not having been officially FDA approved. Every minute of every day there are so many patients stuck in this quagmire, they cannot get into a phase 3 clinical trial because it is closed, and do not have another more humane option because even if the drug was successful in that trial it can take 6-12 months to obtain FDA approval.

This process has to change immediately, because the potential advances in cancer taking place currently and in the near future should completely change the way some cancers are treated. It is now actually possible to envision the day that certain cancers will not necessarily be cured, but at least controlled like a high cholesterol level so that some individual can still live a full life. I am also able to envision for the first time in my life the day that specific cancer preventive vaccines are given to women and men, and in some cases in individuals not much older than my son or daughter, that will improve the chances that individuals will live longer and better lives.

However, all of this hope and optimism is somewhat fueled by past and ongoing tragedies. My 38-year old cousin died in 1997, one year after she was diagnosed with breast cancer, and after talking to literally thousands of cancer patients around the world since then that were running out of options, I am haunted daily by the thought of why someone that has run out of hope cannot gain access to a hopeful drug that could immediately improve the quality or quantity of their life. This is what happened to my cousin for example. All of these medications that are now standard for aggressive breast cancer, but she could not access them because they were in closed clinical trials or waiting to be FDA approved? And, I have witnessed this scenario play out regularly with almost any form of cancer, including and especially prostate cancer.

I am inundated by requests for help. How is this possible? Perhaps, some might counter argue that a promising drug may not be the answer for every patient, but I contend that to not even been provided the information or the opportunity to gain access to promising medications when everything else has failed is what seems so counterintuitive to basic patient rights and quality of care.

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What may truly shock you is that there is really no major obstacle to making any of this happen right now! The pharmaceutical company in most cases does want to make the drug, especially if it is a pill, available early for little to no charge, the FDA even provides a pathway to make the drug available (called "Expanded/Early Access Program" or "EAP" or sometimes known by others as a "compassionate care program"), and the health care professionals in most cases want to get the drug to patients, so what the is the problem here?

The problem is that there is no formalized, organized or united process to make this happen. Individually, we are holding different key pieces of this puzzle, but in reality if we just unify, there will be more than enough pieces to resolve this situation, not just with prostate cancer, but most cancers. It is really that easy in my opinion. In other words, the moment we all come together on this issue, then immediately lives will change.

Let me give you a classic and remarkable recent example that few people were even aware of until now. I, along with many others regularly called the Johnson and Johnson/Centocor Ortho Biotech, Inc pharmaceutical company in 2010 to beg them to make the drug abiraterone (now known as "Zytiga") available early for patients with advanced prostate cancer that were running out of options. Personally, I had multiple conversations with marketing, call control center personal, and even scientists at the company. In the Fall of 2010, abiraterone no longer had a phase 3 trial open and we heard that their phase 3 trial was successful, but we also knew it could take 6 months or longer to get the drug FDA approved and that is exactly how long it took (received approval on April 28, 2011), so what were desperate patients suppose to do?!

Unbelievably in October, the company announced that it was making their pill available across the country for desperate patients! Wow! Was it all the phone calls? Who knows and who cares but paperwork had to be filled out and small monitoring or clinical sites were opening all around the country working with local doctors. We were getting calls from desperate families to determine how they could get the drug. Some men I know were easily able to get it, and others that I know died waiting for it to become available in their region, but at least it was a major first step in believing that what happened with abiraterone and the companies that work with this drug should not be the exception but the rule!

So, first I want to recognize the wonderful gesture and opportunity that was provided by the companies that make abiraterone, but at the same time I want this to serve as an example of what we are able to accomplish together and how we can improve this situation immediately.

Therefore, I have assembled a preliminary and organized diverse patient and health care professional advocacy committee that will meet with some of the pharmaceutical companies on a regular basis to urge them to make their promising drug available for an EAP if their product appears or is successful.

We will regularly meet with company representatives to open the door to all sorts of access, not just for the drug itself, but hopefully helpful insurance coverage information, and how to find a doctor that can help get these medicines to patients immediately.

Regardless, I believe we will be immediately successful, we will provide new hope for families around the world, we will provide a paradigm that will be used in prostate and all other cancers in a short period of time, and all I ask is that you support this concerted mission in some way in the near future, either through prayer, verbal, written, monetary or whatever other way you can think of helping.

All my best,

A handwritten signature in black ink, appearing to read 'Mark A. Moyad', written in a cursive style.

Mark A. Moyad, MD, MPH
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