The Standstill in Medical Advancement and The 21st Century Cures Act



Fig. 1 Cancer and its effects. Ruddy, Kathleen. "Human Hair Wigs for Cancer Patients." *Breast Health and Healing*. N.p., n.d. Web. 20 Mar. 2015.

The United States of America is a powerful country because of a substantial combination of technological advancements and knowledge. However, despite the vast expertise in numerous fields and industries, many innocent Americans suffer incurable diseases that include diabetes, Alzheimer’s, and cancer. Such diseases without a cure greatly impact the lives many and cause deaths of millions. As seen in Figure 1, cancer causes conditions that include progressive weakness and exhaustion, weight loss, and degradation of conscious abilities. According the American Cancer Society (ACS), cancer alone had 6 million estimated new cases in the U.S and 35% (about 585,000 people) of people with the disease suffered death just last year (ACS, “Cancer Facts and Figures 2014”). With extensive knowledge and technology, surely incurable diseases such as cancer should be able to have some sort of cure or treatment by now. Yet, the lack of improving medical therapy stems from the flawed transition from applying knowledge into actual practice. This is because the early venture medical capital industry in America does not acquire enough funding to further push innovative medical devices and therapies into real-world usage.

There are two main causes with these issues that are both legislative. One cause is the U.S Food and Drug Administration’s (FDA) outdated regulatory approval process for medical capital. The regulatory approval that is given to drugs and devices serves as a green light to investors to fund these projects. Investors want to maximize profit; thus, they sponsor projects that have potential and practical applications, and the FDA signifies projects that do so. The problem with the FDA’s regulatory approval process is that it is outdated; early venture medical capital approval can take up to a decade and can cost millions of dollars. This leaves many high potential projects with a long waitlist and years of neglect, which then creates a standstill in project funding and medical advancement overall. Another main cause of the lack of funding for medical projects is the Center for Medicare and Medicaid Service’s (CMS) source of reimbursement uncertainty. Healthcare reimbursement has been transitioning toward the Bundled Payment Program, which reimburses health care providers, such as doctors and hospitals, a certain amount for clinical care for a single condition. Because of this method of reimbursement, doctors develop a mindset of cutting costs and have no incentive to use medical projects that are not deemed necessary. These two legislative issues cause medical innovations and small businesses that create such projects to struggle with obtaining the necessary funding, which then creates a halt in overall medical advancement as medical devices and therapies will not reach the hands of a patient with an incurable disease.

History of the standstill of medical device funding started with the approval of the Medical Device Regulation Act of 1976 under the Ford administration. The Act defines what a “medical device” is, classifies the medical device by risk, and outlines the regulatory process of the medical device by class. Emergo, a medical device consultation organization, notes that with the Medical Device Act, the FDA has the power to ban devices (Emergo, “A Brief History of US Medical Device Regulation”). After about 40 years after this piece of legislation was passed, technology advanced to greatly change what is considered a medical device today, rendering the Act’s definition of a medical device irrelevant. Senators Deb Fischer and Angus King explain, “Today's statutory definition of a medical device — one written almost four decades ago — gives the FDA jurisdiction over nearly "any instrumentality" used in the diagnosis or treatment of a patient” (Fischer & King, “FDA’s slow process hurts innovation: Column”). Because medical devices today are presented through new forms of technologies, such as phones and computers, there are more and more products that undergo the slow regulatory process. Thus, the FDA takes a huge burden on the standstill of medical advancement, as illustrated in this political cartoon by an artist G. Perazza in Figure 2, the FDA has many issues that need to be addressed, and reform is definitely needed. More products that are in a long waitlist to be reviewed and approved accumulate with time, which makes the overall advancement of medical therapy to seem very minimal over the years.

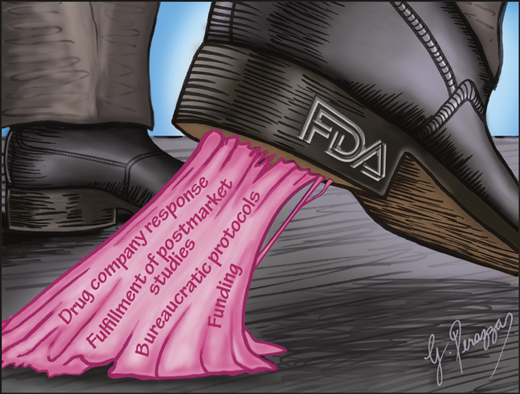


Fig. 2 FDA’s Problems. Perazza, G. Mitka, Mike. "FDA Takes Slow Road Toward Withdrawal of Drug Approved With Fast-Track Process." *JAMA Network*. JAMA Network, 9 Mar. 2011. Web. 21 May 2015.

To solve the legislative issues, it would make sense to directly target the root causes and have the FDA and CMS revise their policies to greatly decrease the time spent on transitioning medical projects from thought to practice; thus, the Parallel Review Pilot Program provided by the government organizations was created in the year 2010. The program seeks five innovative medical projects that meet a certain criteria. The medical device will undergo the faster approval process if it has pre-investigational device exemption, an application for premarket approval, or if it meets Part A or Part B of the Medicare benefit category and is not covered nationally (FDA, “FDA-CMS Parallel Review). Because products that undergo the Parallel Review program receive attention from both government agencies simultaneously, medical innovations under the process are prioritized and should be able to go to market faster. Under the original FDA regulatory approval process, it took about a decade to finish, to which a medical innovation can still be denied the approval to go to the market. However, the Parallel Review Program may seem to be the ideal solution to the standstill in medical innovation funding as it attacks the root cause of the long waiting period small businesses and their products experience.

The Parallel Review Program was successful in approving Cologuard, a technology that detects colorectal cancer. Cologuard received FDA market approval and the national coverage decision (NCD) by the CMS. On the Avalere website, a group of innovative thinkers within the healthcare community, the process of Parallel Review was reported to reduce the NCD timeline by around six months (Avalere, “Notable Success for Parallel Review Program, but Uncertainty about Program’s Future”). The success and positive experience that Cologuard went through with the program suggests the program’s high potential in reducing approval and coverage time for companies and their products.

Although the Parallel Review Program has the ability to greatly reduce the time it takes for products to be approved, it also has many flaws. Edward Berger, a reimbursement strategist for life science companies, critically evaluates the flaws of the Parallel Review Program. In a blog post, Berger clarifies that the program, firstly, can only review up to five products a year. Five products out of a vast amount of innovative projects seems highly negligible. Secondly, companies that wish to seek coverage should consult the CMS prior to parallel review because it would further shorten the time to get their product to the market. Finally, Berger warns that there is a very difficult, but very coherent, set of criteria a company and its product needs to have to actually qualify for parallel review (Berger, “How useful is FDA-CMS parallel review?”). Overall, companies would not want to apply for the Parallel Review program because of the difficult criteria, the low amount of products that are approved, and extra work companies would have to do when consulting the CMS for coverage data.

Rachel Lindor, a medical and law graduate from Arizona State University that seeks to reform healthcare, highlights further flaws of the Parallel Review program. Lindor states, “The lack of wider participation may be due to the novelty of parallel review, which could be perceived as simply substituting one kind of uncertainty for another”. Because the program is relatively new, companies would not want to apply because of uncertainty after approval. Companies and their projects are not sure if they would receive funding from investors since investors are uncertain about the program and its effects. Also, the parallel program can highlight the negative NCD that can affect the profit that small businesses receive if their innovation is not covered nationally.

Overall, the Parallel Review Program in its pilot form by the FDA and CMS has great potential as it attacks the root cause of a lengthy outdated regulatory and reimbursement process that medical projects undergo; however, it is thoroughly flawed. Although the Parallel Review Program had a good attempt at fixing the problem by singling out the root cause, it isn’t very effective. The Parallel Review Program is what America has at the moment, and its approval of about two products within the last five years is rather insignificant and proves its flaws. On the bright side, there is a new piece of legislation that is going through government right now, Bill H.R.6, the 21st Century Cures Act. This piece of legislation, which was created around April 2014, has bipartisan support and is lead by Republican Fred Upton from Missouri and Democrat Diana DeGette from Colorado. After quite a long period of revision of the bill, the 21st Century Cures Act will be reintroduced by the E&C on May 19, 2015. The 21st Century Cures Act aims to improve the transition from the “discovery of clues in basic science, to streamlining the drug and device development process, and unleashing the power of digital medicine… at the treatment delivery phase”, says the U.S House Energy and Commerce Committee (E&C) (E&C, “Energy and Commerce Cures”). The 21st Century Cures Act seeks to solve the standstill in medical advancement, while updating laws to meet the substantial output of innovation and increasing the interactivity of technology within the medical industry.

The 21st Century Cures Act seeks to solve the root problem of a long waiting period that companies face when they want to get their products into the market for sale and usage. Under Title II Subtitle K, the bill proposes a more efficient and accelerated way for breakthrough devices to obtain prioritized review. In a white paper of the bill from the E&C website, Subtitle K of Title II states that devices that have advanced technology and purpose should have prioritized review (E&C, “Discussion Draft”). Of course this is the solution to the main problem of having an outdated regulatory approval review process provided by the FDA. With the outdated process, breakthrough devices would be left in the dust, wasting more and more time before it actually makes an impact in the medical field. However, there is another key important factor that is included in the white paper of the bill, which is the interest of the patient. Under the bill, priority review is not granted only to breakthrough devices with innovative technologies, but it is also granted for devices that best suit the needs for the patient that needs it. This key factor of the bill targets the root effect of the problem, patients that are suffering incurable diseases. The bill recognizes that although many medical innovations thrive in technological advancements, they do not necessarily meet the needs of a patient with a certain type of disease. Thus, the interest of the patients is also focused in the bill, hoping to relieve the patient of his/her suffering with the accelerated review of devices that best suit their needs. Overall, a small section of the 21st Century Cures Act aims to directly solve the issue of a long review period for medical devices. Alexander Gaffney of The Regulatory Affairs Professionals Society (RAPS) states that under the bill, accelerated access will be provided by sponsoring a medical device or a drug with a group of reviewers that are to have shorter clinical trials for the device or drug (Gaffney, “Regulatory Explainer: The (Updated) 21st Century Cures Act). Faster, more convenient, and patient-motivated actions are what this section of the whole bill is concerned with. Of course, confronting the origin of the problem is solved under this piece of legislation, but the bill also helps alleviate other externalities with the standstill in medical therapeutic advancement.

The 21st Century Cures Act is also very convenient as it aims to solve side problems of the overall problem, the slowdown medical advancement in America. The RAPS lists numerous amounts of features to expect from the 21st Century Cures Act. Another worthy feature of the bill, aside from accelerated review for breakthrough devices and drugs, would be the ability for small businesses to have the special exclusivity to sell their own product without fear of competition. “Companies which have an approved drug with an added five years of so-called "qualified infectious disease product" (QIDP) exclusivity will be able to sell up to one year of that exclusivity to another company”, explains Gaffney. Small businesses, although they seem to only have the goal of profit in mind, play a huge role in the advancement of medical therapy. Small businesses overall serve as the bridge from applying knowledge into actual medical practice with the products they make. Without companies and their drive for profit, there would not be actual breakthrough devices to apply to real-world medicine. This aspect of the 21st Century Cures Act proves to be a useful way to create incentives for small businesses to create that genius, breakthrough product. With the exclusivity of selling their own product without competition, more companies would want to create breakthrough devices and gain maximum profit. Thus, the drive for advancing medical therapy is further pushed with the convenient exclusivity of companies selling their own products.

Opposition for the 21st Century Cures Act mainly involves what actually solves the root problem, which would be the accelerated review process of the medical devices and drugs. Dr. David Gortler, a drug reviewer of the FDA states, “Lives could be saved, but more people could also be killed if you rush the drug development process” (Leonard, “Medical Innovation Bill Could Harm Americans Looking for Disease Cures”). The main concern that Gortler has with the bill is that with the accelerated process, carelessness can ensue and the shortened amount of clinical trials can actually hurt the accuracy of determining how helpful the medical device or drug really is. However, with the 21st Century Cures Act, acceleration of product review is not leaving the accuracy of innovation judgment behind. As mentioned before, the product that is being reviewed is assigned a certain team within the FDA for careful, but expedited clinical trials. The aspect to highlight in this change in the review process is not only the quick trials, but also the team that conducts the examinations. With a team, the process of clinical trials are conducted with heightened communication amongst experts, making both communication and teamwork the greatest successful aspect in conducting faster experimental trials on innovative medical devices and drugs.

Overall, the 21st Century Cures Act seems to be the best piece of legislation to support in order to help advance medicine and help find cures for deadly diseases. The FDA-CMS Parallel Review Program is considered a failure as the qualifications to actually achieve parallel review are too difficult to meet and only five products are allowed access to the program a year. With the 21st Century Cures Act, the root problem of having a standstill in funding for medical innovations is targeted with the revised FDA regulatory approval process for all drugs and devices. With expedited review, products can be sent out into the market for investors to sponsor and actual usage in real-world medicine to help increase the effectiveness of overall medicine. Along with an altered review process, there are many more aspects of the bill that help to further strengthen medical therapy. An example of one of many features of the bill would be the exclusivity of companies to sell their products without competition. Because of the 21st Century Cures Act’s great combination of solving the origin of the problem along with solving other aspects surrounding the problem and its solid bipartisan support, the future for medical therapy seems bright, as more and more innovative medical technologies will be brought into the market for usage and cures.

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The statistics provided by the American Cancer Society was used in my paper to try and lure the reader and get his/her attention. The American Cancer Society has been providing details and information about Cancer since its creation in 1913. The ACS has been a widely known organization that supports people suffering cancer by raising funds and also educates people of the dangers of cancer.

Avalere. "Notable Success for Parallel Review Program, but Uncertainty about Program's Future." *Avalere.com*. Avalere Health, 14 Aug. 2014. Web. 26 May 2015.

Avalere’s article exudes the potential benefits and strengths of the Parallel Review Program by providing an example of a medical product that successfully obtained approval through the Parallel Review Program. I use the success of the Parallel Review Program that is highlighted by this article to show the potential that the program has. Avalere Health is an organization of critical thinkers that seek to improve the shortcomings of the healthcare system. The article produced by them has pretty acknowledgeable evidence as the medical device approved, Cologuard, is widely known to be under the Parallel Review Program.

Berger, Edward. "How Useful Is FDA-CMS Parallel Review?" N.p., 25 Aug. 2014. Web. 26 May 2015.

Edward Berger is a reimbursement strategy counselor for early venture capital companies and he writes about the negative aspects of the Parallel Review Program. Difficulty of admission and limited review are the main issues of the program. I use Berger’s blog post to talk about the negative aspects of the Parallel Review program in opposition to the approval of Cologuard. Because Berger is a professional and has worked in this field for numerous years (he previously worked in Medical Development Group and ABIO Med Inc.), he has acquired substantial knowledge about the medical innovation field.

Emergo. "A Brief History of US Medical Device Regulation." *Emergo*. N.p., 23 Sept. 2013. Web. 26 May 2015.

Emergo is a Global Medical Device Consultation organization created in 1997 that breaks down the history of medical device regulation in this article. They provide a series of graphics and cartoons along with a summary of the event that happened in a year. I use this article to provide history for the problem of the medical advancement standstill in America. Information about legislation and medical device regulation is provided in this article.

Energy and Commerce Committee. "Discussion Draft." (n.d.): n. pag. *Energycommerce.house.gov*. Energy and Commerce Committee. Web. 26 May 2015.

The Energy and Commerce Committee is a government organization that has influence and interest over public health. This discussion draft is the white paper of the Bill H.R. 6 or the 21st Century Cures Act. I use this to focus on the other features the bill has along with the accelerated approval process the FDA will have.

Energy and Commerce Committee. "Energy and Commerce Cures." *Energy and Commerce Cures*. N.p., n.d. Web. 26 May 2015.

The E&C white paper emphasizes the overall purpose of the bill H.R. 6 and then goes on to explain the individual goals. Once again, the government organization summarizes the 21st Century Cures Act and provides information regarding the strengths of the piece of legislation. I use this white paper to talk about the overall significance and powers the bill will grant the FDA and other legislative organizations.

FDA. "U.S. Food and Drug Administration." *FDA-CMS Parallel Review*. N.p., n.d. Web. 26 May 2015.

The U.S Food and Drug Administration provides the outlines and requirements for a device to meet to obtain access to Parallel Review under this section of the FDA website. The FDA is a government organization that helps regulate medical drugs and devices.

Fischer, Deb, and Angus King. "FDA's Slow Process Hurts Innovation: Column." *Usatoday.com*. N.p., 15 Feb. 2014. Web. 26 May 2015.

Government officials Deb Fischer and Angus King are advocates for change in healthcare and medical device regulation and coverage. In this article, they highlight the need for the FDA to revise their approval process in order to hasten medical advancement. I use this article in the stating of the problem in order to add significance and government officials’ opinions on the issue of medical devices.

Gaffney, Alexander. "10 Proposals Worth Paying Attention to in the 21st Century Cures Act." *Raps.org*. RAPS, 30 Jan. 2015. Web. 26 May 2015.

Alexander Gaffney is contributor at the Regulatory Affairs Professional Society and talks about ten major features in the 21st Century Cures Act to look out for in the future. I use this article in my essay to further exemplify the great foundation the bill has on reforming medical device regulation by analyzing aspects other than the accelerated regulation process.

Gaffney, Alexander. "Regulatory Explainer: The (Updated) 21st Century Cures Act." *Raps.org*. RAPS, 30 Apr. 2015. Web. 26 May 2015.

Alexander Gaffney and RAPS provide a summary of the H.R. 6 bill and analyzes the strengths of the 21st Century Cures Act. In my essay, I use this source to further analyze the significance of an accelerated regulatory approval process is to attacking the causation of the overall problem of a standstill in medical advancement.

Leonard, Kimberly. "Medical Innovation Bill Could Harm Americans Looking for Disease Cures." *US News*. U.S.News & World Report, 1 May 2015. Web. 26 May 2015.

Kimberly Leonard is a health care reported at *U.S News* and provides the public with knowledge about trending issues and topics regarding healthcare of the United States. I use her article to provide opposition on the 21st Century Cures Act; however, her opposition does not have a great impact as it is explained away by the bill reforms. Kimberly Leonard has been reporting healthcare issues for a while as she previously reported for Health Rankings.

Lindor, Rachel. "Regulatory and Reimbursement Innovation." *Sciencemag.org*. N.p., 13 Mar. 2013. Web. 26 May 2015.

Rachel Lindor is one of six graduates in Arizona State University to graduate with a medical and law degree. She is pursuing a career that involves reforming and attacking the issues of United States healthcare. In this article, she provides the flaws of the FDA-CMS Parallel Review Program. I use this article to further highlight the flaws of the Parallel Review program.