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CONSUMERS FOR
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Free To Choose Medicine in Japan: A Model for America

By Edward Hudgins, Ph.D.

Summary

- Faced with the need to deliver therapies quickly to patients, Japan adopted the Free To Choose Medicine (FTCM) model for cutting-edge tissue-based cures.
- FTCM creates a second track to traditional government certification processes, cutting off years of wait times for patients seeking safe, promising treatments.
- If the United States wants to spare its citizens much suffering and save lives, it should learn from Japan and adopt FTCM.

Executive Summary

The twenty-first century might well see medical innovations that could rid humanity of crippling and deadly illnesses, extending the healthy lifetimes of all by decades. If, however, you're an American, you might have to travel to Japan to take advantage of these breakthroughs.

In recent decades, the time and costs required to obtain new medications, treatments, and therapies have increased significantly. One cause of these increases is the slow government approval process. Many patients suffer and even die because they cannot access treatments held back by government. Further, many of the new and most promising regenerative medicine products do not fit into existing regulatory regimes.

Japan faced these and other challenges. That country's researchers were calling for reforms and its aging population made the need for better treatments for the elderly imperative. Fortunately, Japanese policymakers had at hand the right idea at the right time: Free To Choose Medicine (FTCM), which creates an alternative to traditional government certification processes. Free To Choose Medicine can cut years off the approval process of medical treatments and therapies compared to the current system in the United States.

In late 2014, Japan passed two new laws. One law adopted the FTCM regime for regenerative medicine products that could be reimbursed under that country's health insurance system. The second law set new

rules for cell and tissue-based treatments that are provided by private clinics not reimbursed by the Japanese health insurance system. These clinics had not fallen under the old approval regime and do not fall under the new FTCM model. In late 2017, lawmakers fine-tuned the regulations set forth in the second law to ensure safety and efficacy.

The United States is the world's leader in medical innovations, but Japan has become the innovative world leader in creating a drug-approval process that quickly makes medical breakthroughs accessible to the patients who need them the most. American policymakers need to learn from the Japanese example to ensure U.S. medical innovators do not lose their competitive edge and that the goal of these innovations is achieved: preventing and curing illnesses.

JAPAN HAS BECOME THE INNOVATIVE WORLD LEADER IN CREATING A DRUG-APPROVAL PROCESS THAT QUICKLY MAKES MEDICAL BREAKTHROUGHS ACCESSIBLE TO THE PATIENTS WHO NEED THEM THE MOST.

The Need for Reform

Medical costs in America, as well as virtually everywhere else in the world, have been rising for decades, and the high costs associated with developing new drugs and medical treatments contribute to these increases. For example, a Tufts University study found in the United States it usually takes a decade to develop and approve a new drug, costing on average $2.6 billion.[1] Much of that delay is due to antiquated U.S. Food and Drug Administration (FDA) efficacy certification requirements.

After researchers develop what they think is a promising drug, the drug is tested on about 20–100 volunteers for basic safety during FDA's Phase I drug-approval stage. Often at this early phase, it is apparent which products are the most promising. The process doesn't end there, however.

FDA's Phase II involves as many as 500 patients who suffer from the ailment the drug targets. The primary goal of Phase II trials is to determine a trial drug's general efficacy and side effects.

Phase III involves as many as 5,000 patients, though often less, and refines the understanding of the product and its dosages.[2] During the standard randomized clinical tests required in the latter phases for efficacy, usually half the test participants receive the medication under review while the other half receives placebos.

After these three phases are complete, manufacturers can submit a New Drug Application to FDA, which then decides whether to approve the product.

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[1] Rick Mullin, "Tufts Study Finds Big Rise In Cost Of Drug Development," *Chemical & Engineering News*, November 20, 2014, Vol. 92, Issue 47, p. 6, https://cen.acs.org/articles/92/i47/Tufts-Study-Finds-Big-Rise.html.

[2] Bartley J. Madden, *Free To Choose Medicine*, Third Edition (Arlington Heights, IL: The Heartland Institute, 2017), p. 20.

Japan and other countries use similar processes for approving drugs, which come with several serious drawbacks: First, in the United States, the three phases can take six to 11 years to complete, adding to the already high cost of medicine.[3]

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Second, the sick patients participating in the clinical tests who receive placebos might not be on the path to recovery.

Third, patients who are not given an opportunity to use trial drugs, which are safe and often promising, might endure needless suffering or even die.[4]

Fourth, because the costs of bringing new treatments to market are high and because manufacturers cannot earn back their investments during the testing period, many manufacturers are from the start discouraged from investing the large sums necessary to discover new treatments.

Added to these problems is that certain characteristics of tissue-based therapies make many aspects of the traditional trial process unnecessarily burdensome to complete. Traditional medicines are compounds of chemicals and various substances meant to prevent or cure illnesses. Tissue-based therapies contain or consist of human cells that might have been modified or manipulated in some way. For example, immune cells from a donor might be engineered to target, turn off, or destroy cancer cells in a sick individual.[5] A similar approach can be used to treat some blood disorders.[6] The traditional clinical testing approach of giving placebos to half the test group—and other mandated approaches imposed by government agencies—are often irrelevant to determining the efficacy of tissue-based treatments.

Japan's Road to Reform

Japan is the second-largest market for pharmaceutical products in the world, with about $106 billion in annual sales.[7] (The largest market is in the United States.) Prior to making

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[3] *Ibid.*

[4] For examples, see the website for the Abigail Alliance, a group that documents such tragedies and advocates for easier access to medications now kept from patients by the Food and Drug Administration's certification process: http://abigail-alliance.org/.

[5] Jane Kirby, "Layla Richards: One-year-old girl becomes world's first person to receive therapy to cure 'incurable' cancer," *The Independent* (U.K.), November 5, 2015, https://www.independent.co.uk/news/people/layla-richards-one-year-old-girl-becomes-worlds-first-person-to-receive-therapy-to-cure-incurable-a6723226.html.

[6] Charlotte Dean, "Humans will be genetically modified for the first time in Europe as scientists get the go-ahead to use DNA-splicing therapy to treat blood disorder," *The Daily Mail*, April 15, 2018, http://www.dailymail.co.uk/news/article-5618061/Humans-genetically-modified-time-Europe.html#ixzz5Fs3HrLZx.

[7] "The Pharmaceutical Industry and Global Health: Facts and Figures 2017," International Association of Pharmaceutical Manufacturers & Associations, p. 68, https://www.ifpma.org/wp-content/uploads/2017/02/

significant changes to its approval process for regenerative medicine products, many factors placed Japan on the road to reform, including the five listed below.

MANY FACTORS PLACED JAPAN ON THE ROAD TO REFORM, INCLUDING THE FIVE LISTED BELOW.

First, new tissue-based therapies did not fall under Japan's traditional regulatory regime. There were concerns about potential harms such therapies, if not vetted in some way, could cause for patients, and some feared Japan could become a tourist destination for patients seeking to access untried, possibly dangerous products.

Second, it was recognized that regenerative medicine, notably stem-cell therapies, "is an important component of healthcare strategy in Japan"—especially with its aging population—and that such treatments need to be facilitated.[8] About 26.5 percent of Japan's population is older than 65, about 33.5 million of that country's 126 million people, the largest proportion of elderly people in any country's population in the world.[9] Life expectancy in Japan is now 83.7, one of the world's highest.[10] Most medical problems and the associated costs occur in old age, both in Japan and in other developed countries, making quick access to regenerative medications and therapies in Japan imperative.

Third, there was an appreciation among Japanese researchers, voiced in the 2012 "Yokohama Declaration" by the Japanese Society for Regenerative Medicine, of the need for efficacy evaluations other than "randomized controlled trials" and for "early approvals with an emphasis on post-market clinical evaluations."[11] This was a recognition that clinical trials are often not the best way to judge the efficacy of medical and therapeutic innovations.

Fourth, South Korean authorities, just prior to Japan's reforms, had approved three stem-cell products when Japan had no such prospective products.[12] The Japanese policymakers understood they were falling behind to a regional competitor.

Fifth, there was a need to create a process that

IFPMA-Facts-And-Figures-2017.pdf.

[8] Kenji Konomi *et al*., "New Japanese Initiatives on Stem Cell Therapies," *Cell Stem Cell*, Vol. 16, Issue 4, April 2, 2015, p. 350, www.cell.com/cell-stem-cell/pdf/S1934-5909(15)00123-X.pdf.

[9] "Countries With The Largest Aging Population In The World," *World Atlas*, accessed May 21, 2018, https://www.worldatlas.com/articles/countries-with-the-largest-aging-population-in-the-world.html https://data.worldbank.org/indicator/SP.POP.65UP.TO.ZS?contextual=population-by-age&locations=JP&name_desc=false http://www.who.int/gho/publications/world_health_statistics/2016/EN_WHS2016_AnnexB.pdf?ua=1.

[10] "Japan has the highest life expectancy," World Health Statistics 2017, May 17, 2017, http://www.who.int/kobe_centre/mediacentre/whs/en/.

[11] Douglas Sipp, "Conditional Approval: Japan Lowers the Bar for Regenerative Medicine Products," *Cell Stem Cell*, Vol. 16, Issue 4, April 2, 2015, p. 353, http://www.cell.com/cell-stem-cell/pdf/S1934-5909(15)00124-1.pdf.

[12] *Ibid*., p. 354.

would allow innovators to be reimbursed for new therapies by the Japanese national health care system.

The Role of Free To Choose Medicine

Faced with these challenges, Japanese policymakers still might have been at a loss about how to proceed. Fortunately, the right idea at the right time was available: Free To Choose Medicine, an innovative approach developed by Bartley Madden that would create an alternative pathway to traditional government drug certification, granting patients access to safe and promising treatments earlier and allowing physicians and patients to make sounder judgements about the efficacy of treatments.[13]

Fortunately, the right idea at the right time was available: Free To Choose Medicine, an innovative approach developed by Bartley Madden.

Masaru Uchiyama, president of Japanese for Tax Reform, explained that he heavily promoted a 2007 Japanese translation of an early version of Madden's FTCM book "to government ministries and agencies, pharmaceutical companies, medical equipment manufacturers, [nongovernment organizations] critical to government policy, pharmacodynamics litigation organizations, etc."[14] He observed local government officials offered support for this approach at parliamentary study meetings.

The influence of Madden's FTCM plan is evident from some of the criticisms of the Free To Choose Medicine model. For instance, in a June 16, 2014, article in *Nature*, Paolo Bianco and Douglas Sipp, in their criticism of the FTCM approach, wrote, "Think tanks in the United States are using stem cells to promote broader deregulation; these moves are influencing policy in other countries." The authors further observed, "Under the Free To Choose Medicine campaign put forward in 2010 by the Heartland Institute in Chicago, Illinois, US companies would be able to sell drugs after small clinical trials that are insufficient to establish either safety or efficacy."[15]

The authors were mistaken in their understanding of FTCM and the safety of such a model, but it's clear they acknowledged FTCM's far-reaching influence and it origins.

In September 2014, Japan passed two laws to update its approval system: (1) the Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (PMDA), which was based on FTCM, and (2) the Act on the Safety of Regenerative Medicine (ASRM), which covered products developed by private clinics outside

[13] Bartley Madden, *supra* note 2.

[14] Email exchange between Masaru Uchiyama and Edward Hudgins, February 16, 2018.

[15] Paolo Bianco and Douglas Sipp, "Sell Help, Not Hope," *Nature*, Vol. 510, June 19, 2014, p. 336, https://www.nature.com/polopoly_fs/1.15409!/menu/main/topColumns/topLeftColumn/pdf/510336a.pdf.

the PMDA regime. The laws took effect in November 2014.[16]

In a 2015 *Cell Stem Cell* journal article, Sipp acknowledged that those new laws were a move "toward market-based schemes similar to those that have recently been promulgated by free-market advocacy groups in the United States and other countries," and he linked to his earlier article citing FTCM and Heartland.[17]

What the Two Laws Do

Japan's two reform laws cover separate areas of research and therapy.

PMDA created a new pathway to obtain conditional and time-limited drug approval meant specifically for regenerative medical products—that is, cellular and tissue-based therapies, including stem-cell therapies, which are reimbursed through the country's national health care system. PMDA did not directly impact existing rules for more traditional medications. (Some writers refer to research involving "induced pluripotent stem cells iPSCs" as an "important component of healthcare strategy in Japan."[18] These are non-embryonic cells and thus avoid a possible area of ethical controversy. ASRM, discussed below, explicitly regulates somatic stem-cell therapies, which are also non-embryonic.)

PMDA is modeled after FTCM. Under PMDA, treatments are made available to patients after Phase I safety approval. Conditional and time-limited approval is available for up to seven years. A product or treatment, however, must still ensure product effectiveness to the satisfaction of Japanese regulators.

Scholars reviewing PMDA note the limits of traditional clinical tests. As one scholar notes, the PMDA reforms not only accelerate access to products and therapies but also "shift the determination of efficacy from premarket clinical trials to a … post-market mechanism."[19]

PMDA is modeled after FTCM. Under PMDA, treatments are made available to patients after Phase I safety approval.

Of significant importance, the Japanese reforms of PMDA were meant to facilitate the collection of and access to data based on market use. A central benefit of the FTCM system is its Tradeoff Evaluation Drug Database (TEDD). TEDD provides a mechanism for collecting real-world data as patients try different medications or therapies. Japanese regulators are now authorized to establish a similar system, composed of patient data. As patients use conditionally approved therapies outside the

[16] For a simple English-language summary, see Taisuke Hojo, "New Regulation in Japan and Future Direction of PMDA," PowerPoint presentation, Pharmaceuticals and Medical Devices Agency, n.d., https://www.pmda.go.jp/files/000204615.pdf.

[17] Douglas Sipp, *supra* note 11.

[18] Kenji Konomi *et al.*, *supra* note 8.

[19] Douglas Sipp, *supra* note 11.

standard clinical testing track, the results can be placed in that registry, where names and other private information are shielded from researchers' view.

This approach benefits patients, innovators, and regulators seeking to ensure patient safety. A look at the diagram of the traditional approach to approval and the new approach in Japan indeed looks like a diagram of the FTCM system. (See the Appendix on page 11.)

The Japanese government has also committed to investing additional funds in regenerative therapies.

POLICYMAKERS PASSED ASRM TO ADDRESS THE POTENTIAL PROBLEM JAPAN MIGHT BECOME A HAVEN FOR MEDICAL TOURISTS SEEKING UNAPPROVED AND POSSIBLY DANGEROUS STEM-CELL TREATMENTS.

ASRM introduced a "risk-based registration and approvals process for the use of cell-based interventions by private physicians who do not distribute products or seek reimbursement [from the country's health insurance system], thereby avoiding regulation by the PMDA."[20] Policymakers passed ASRM to address the potential problem Japan might become a haven for medical tourists seeking unapproved and possibly dangerous stem-cell treatments.

Under ASRM, parties offering regenerative therapies must seek review from the Certified Committee for Regenerative Medicine. Requirements for approval vary based on the therapy class. After a preliminary evaluation and approval, certain therapies must go to the Ministry of Health, Labor and Welfare.[21]

ASRM Revisions

Since the reform laws took effect in late 2014, Japanese officials have worked to set up the mechanisms to administer them. Several therapies have been submitted under the PMDA regime.[22] For example, "HeartSheet and Temcell HS Injection are subject to reimbursement under the universal healthcare system as of January 2016 and November 2015, respectively."

In April 2018, Trinity Clinic Fukuoko began offering the first stem-cell therapy for Alzheimer's disease. The therapy, developed by a South Korean lab, was classified in a low-risk category under ASRM, and therefore only needed to receive approval from a review board. In March 2018, the Kyushu Certified Special Committee for Regenerative Medicine signed off on the therapy. In line with ASRM, the Ministry of Health, Labor and Welfare was notified and it registered the review board's

[20] *Ibid.*, p. 354.

[21] Douglas Sipp and Hideyuki Okano, "Japan Strengthens Regenerative Medicine Oversight," *Cell Stem Cell*, Vol. 22, Issue 2, February 1, 2018, p. 154, https://www.cell.com/cell-stem-cell/abstract/S1934-5909(18)30001-8.

[22] Akihide Konishi *et al.*, "First Approval of Regenerative Medical Products under the PMD Act in Japan," *Cell Stem Cell Letters*, Vol. 18, Issue 4, April 7, 2016, p. 434, http://www.cell.com/cell-stem-cell/pdfExtended/S1934-5909(16)00117-X.

approval. The clinic began offering the therapy soon thereafter.[23]

There are concerns about ASRM. One of the most common complaints is that regulations governing private providers are too loose and that patient safety is endangered as a result.[24] There has been police action, including some arrests in 2017, against individuals accused of offering therapies outside the ASRM system.

A second criticism of ASRM is that it might be difficult to recruit patients under the PMDA regime if the ASRM option allows clinics to get treatments they are developing to patients even quicker than through PMDA, though without the adequate testing for safety. This could deter companies from investing in new research and could create long periods before a potential product can be brought to the marketplace, even under the expedited PMDA regime and even if companies are reimbursed for providing therapies.

Of the 3,717 submissions made under ASRM, 3,486 were for therapies and only 126 sought approval for research.[25]

In late 2017, Japanese officials announced plans to tighten regulations on private providers of stem-cell and other regenerative therapies. Other countries—including Australia, India, and the United States—have made similar efforts to tighten oversight through the rulemaking process.[26]

Despite the fact these treatments are not reimbursed by Japan's health care system, they have attracted numerous patients, which might seem counter-intuitive to some. This is a testament to the significant demand for currently unapproved products. It is also undoubtedly proof of the fact private clinics have focused more on attracting patients while more conventional companies have—at least prior to the passage of the reforms—focused on research and government approval for their therapies using traditional clinical testing procedures. These conventional companies now find themselves in new territory, and there is a learning curve for them and the public.

ONE OF THE MOST COMMON COMPLAINTS ABOUT ASRM IS THAT REGULATIONS GOVERNING PRIVATE PROVIDERS ARE TOO LOOSE AND THAT PATIENT SAFETY IS ENDANGERED AS A RESULT.

The Context of Reform

A goal of FTCM reform is to facilitate the collection of real-world data to assist researchers, patients, and physicians in making the best judgements concerning the development and

[23] Sohn Ji-young, "Nature Cell's stem cell treatment for Alzheimer's approved in Japan," *The Korean Herald*, March 20, 2018, http://www.koreaherald.com/view.php?ud=20180320000783.

[24] Douglas Sipp and Hideyuki Okano, *supra* note 21, pp. 153–155.

[25] *Ibid.*, p. 154.

[26] *Ibid.*

distribution of treatments. Japan will develop its TEDD system in the context of another significant reform concerning data collection.

In 2017, Japanese lawmakers passed the Act Regarding Anonymized Medical Data to Contribute to research and development in the Medical Field, also called the "Next Generation Medical Infrastructure Act." It took effect in May 2018.[27] It creates a mechanism by which patients' experiences with drugs can be collected and pooled efficiently and made available to researchers, especially to help those working on using artificial intelligence to analyze "big data."[28] The system allows private companies to perform the time-consuming process of removing from the records of participating physicians and institutions patient names and other information that would jeopardize patient privacy and to assemble data in a form most useful for researchers.

Perhaps another indication of the spirit of reform in Japan and its ripple effects is the recent approval by Japanese regulators of a new medication called Radicava, which is used to treat amyotrophic lateral sclerosis (ALS).[29] This treatment is a traditional medication, not a tissue-based treatment, yet the U.S. FDA quickly bypassed its own established approval process and asked the manufacturer to submit a New Drug Application without forcing it to go through every stage of FDA's three-phase, multi-year trial system. FDA quickly approved the drug, thereby permitting into the U.S. marketplace for the first time in 22 years a new product to treat ALS.

Highlighting the international context of the need for reform of government approval processes for medicines and therapies, a Canadian news service featured a story of a citizen of that country traveling to Japan to secure this medication, which was not yet approved for use in Canada.[30]

The quick acceptance by the FDA of this ALS treatment, which was based on the prior approval of Japanese regulators, might suggest the need for reciprocity agreements between advanced countries for drug approval. Why should Americans (or Canadians) have to travel overseas to treat illnesses with medications or therapies declared safe in other countries? Even more, the ALS example illustrates why it would be prudent for the United States to adopt FTCM for traditional and tissue-based therapies.

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[27] Tomoko Otake, "Medical big data to be pooled for disease research and drug development in Japan," *The Japanese Times*, May 15, 2017, https://www.japantimes.co.jp/news/2017/05/15/reference/medical-big-data-pooled-disease-research-drug-development-japan/#.WwVXNEgvw2y.

[28] John Roebuck *et al.*, "Japan: Enactment Of Next Generation Medical Infrastructure Act," *Mondaq*, July 31, 2017, http://www.mondaq.com/x/615196/Life+Sciences+Biotechnology/Enactment+Of+Next+Generation+Medical+Infrastructure+Act.

[29] Matthew Herper, "The First ALS Drug In 22 Years Is Approved—And It Costs 4 Times What It Does In Japan," *Forbes*, May 5, 2017, https://www.forbes.com/sites/matthewherper/2017/05/05/fda-approves-first-new-drug-to-treat-als-in-22-years/#6bef5de57fb3.

[30] Sonja Puzic, "Patients see hope in new ALS drug not approved for sale in Canada," *CTV News*, August 25, 2017, https://www.ctvnews.ca/health/patients-see-hope-in-new-als-drug-not-approved-for-sale-in-canada-1.3562153.

Conclusion

Advances in medical science have entered a new and fast-moving era. Therapies thought unimaginable just a few decades ago, including therapies based on stem-cell research and biohacking, are becoming more readily available. Illnesses that have plagued humans throughout history are now on the verge of being cured.

FDA Commissioner Scott Gottlieb recently told the Alliance for Regenerative Medicine's annual board meeting, "We're at a key point when it comes to cell and gene therapy. These therapies have the potential to address hundreds, if not thousands, of different rare and common diseases."[31] But just as the efficient production and delivery of other goods and services to consumers require consumer choice in free markets, so too do the production and delivery of pharmaceuticals and therapies.

ADVANCES IN MEDICAL SCIENCE HAVE ENTERED A NEW AND FAST-MOVING ERA.

In May 2018, the United States made a positive step in that direction—as well as toward FTCM—when Congress passed and President Donald Trump signed the Right to Try Act. Versions of this law had already been passed by 40 states. Those states give terminally ill patients the right to try drugs that have passed safety tests but have not yet been approved by the FDA. The new law gives federal approval to those existing state laws and allows those states to administer Right to Try without interference from the FDA. This law is a good start, but much more is needed.

Stemming from a need to spur innovation and provide the best health care for its aging population, Japan has adopted an FTCM regime for tissue-based treatments. This approach is not only helping that country meet its obligations to its own people, it is also challenging other countries to move to such a system as well.

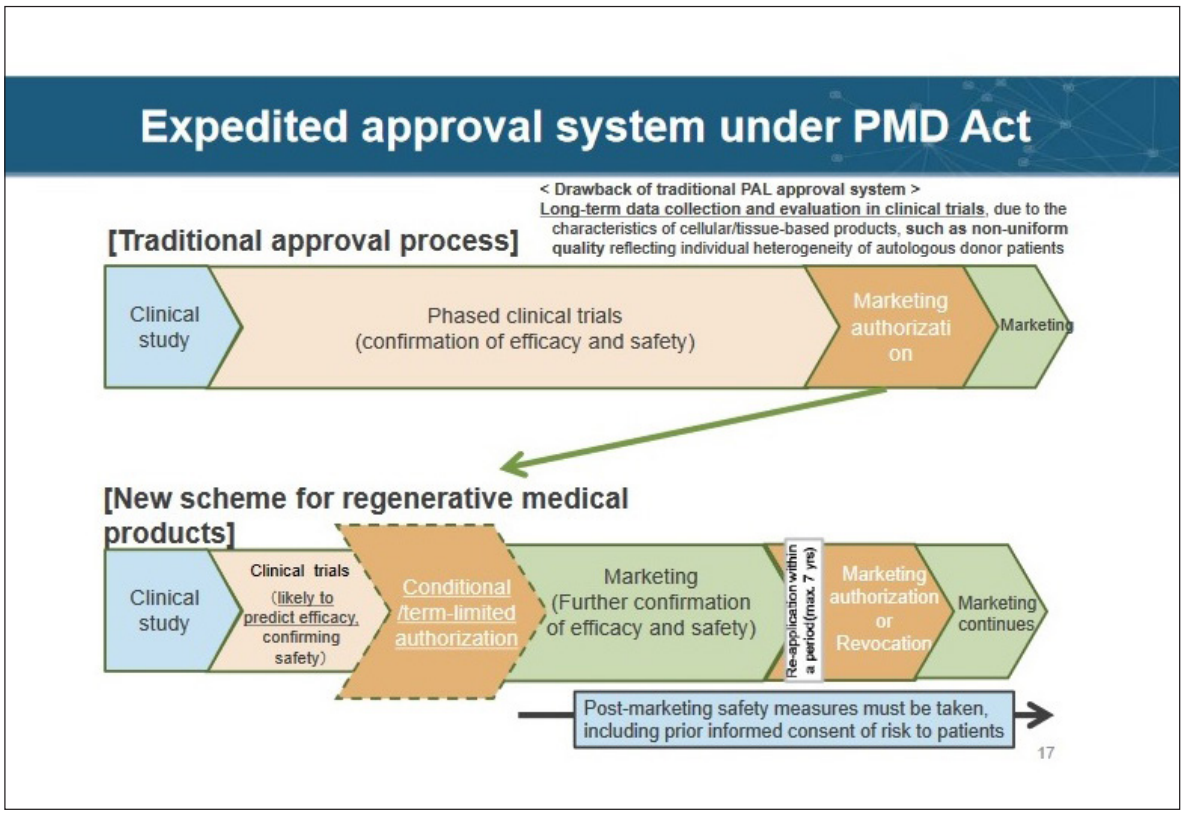
The United States has cutting-edge medical research facilities and experts, and its citizens spend more money on health care than the citizens of any other country. However, to take full advantage of its resources, America needs an innovative approval regime that would maximize consumer access and reduce costs and the time it takes to deliver innovative medicines and therapies. FTCM is that regime.

While FTCM is cutting-edge, it is not a radical and irresponsible approach that will endanger the safety and health of patients. It's quite the contrary, in fact. FTCM would authorize access to treatments already certified as safe and allow for real-world data collection to discover the efficacy of therapies. Most importantly, it would empower individuals with choice so that they need not suffer or die while waiting for years for a slow-moving, broken regulatory system to deliver the treatments they need. If Japan, which has one of the largest pharmaceutical markets in the world, can adopt this innovative approach, why not the United States?

[31] Scott Gottlieb, "Remarks by Commissioner Gottlieb to the Alliance for Regenerative Medicine's Annual Board Meeting," May 22, 2018, https://www.fda.gov/NewsEvents/Speeches/ucm608445.htm.

Appendix

Below is the diagram of the traditional approach to approving tissue-based therapies in Japan and the new alternative that was based in part on Madden's Free To Choose Medicine model.[32] Notice that under the Japanese model, after an initial safety certification is received, a therapy can be granted conditional, term-limited authorization that provides patients access to a new therapy.



[32] Taisuke Hojo, *supra* note 16, p. 17.

About the Author

Edward Hudgins is the research director for The Heartland Institute.

In conjunction with other department directors, Hudgins sets the organization's research agenda and priorities; works with in-house and outside scholars to produce *Policy Studies*, *Policy Briefs*, and books; contributes his own research; and works with Heartland staff to promote Heartland's work.

Before joining Heartland, Hudgins was the director of advocacy and a senior scholar at The Atlas Society, which promotes the philosophy of reason, freedom, and individualism developed by Ayn Rand in works such as *Atlas Shrugged*. His latest Atlas Society book was *The Republican Party's Civil War: Will Freedom Win?*

While at The Atlas Society, Hudgins developed a "Human Achievement" project to promote the synergy between the values and optimism of entrepreneurial achievers working on exponential technologies and the values of friends of freedom.

Prior to this, Hudgins was the director of regulatory studies and editor of *Regulation* magazine at the Cato Institute and a senior economist at the Joint Economic Committee of the U.S. Congress, specializing in trade and regulatory issues.

Hudgins also worked at The Heritage Foundation as deputy director for domestic policy studies and as the director of the Center for International Economic Growth, where he pioneered the concept of an Index of Economic Freedom.

Hudgins has appeared on numerous major TV networks, including CSPAN, Fox News, MSNBC, The History Channel, and CNN, and his op-eds have been featured in papers like the *Washington Times*, *Wall Street Journal*, *Boston Globe*, and *Philadelphia Inquirer*.

Hudgins earned a bachelor's degree in government from the University of Maryland, a master's degree in political theory from American University, and a Ph.D. in political philosophy and international political economy from the Catholic University of America. He has taught at universities in Germany and the United States.

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- We produce four monthly public policy newspapers – *Budget & Tax News*, *Environment & Climate News*, *Health Care News,* and *School Reform News* – which present free-market ideas as news rather than research or opinion.

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