



21ST CENTURY CURES DISCUSSION DOCUMENT SUMMARY – JANUARY 27, 2015

Based on feedback received from patients, innovators, providers, regulators, and researchers during the 21st Century Cures initiative, it is clear that Congress must take bold action to accelerate the discovery, development, and delivery of promising new treatments and cures for patients and maintain our nation's standing as the biomedical innovation capital of the world. Energy and Commerce Committee Chairman Fred Upton (R-MI), along with Rep. Diana DeGette (D-CO), led this important conversation for the past year and with this discussion document begins the #Cures2015 journey to get this done for patients.

The discovery, development, and delivery process is a cycle, meaning that data captured and analyzed on the delivery side informs new discoveries and better, more targeted solutions for patients. While improvements to individual components of this cycle can make a meaningful difference, the United States must ensure that, in its entirety, the cycle is a constantly revolving generator of innovative new treatments and cures. Simply improving the individual components is not enough; we must continually monitor and ensure that the parts work together efficiently.

While the legislative language released today is far from perfect, with the aforementioned goals in mind, the discussion document includes provisions authored by both Republicans and Democrats that would: (1) incorporate patient perspectives into the regulatory process and help address their unmet medical needs; (2) build the foundation for 21st Century medicine; (3) streamline clinical trials; (4) accelerate the discovery, development, and delivery cycle and support continued innovation at our Federal public health agencies; and (5) modernize medical product regulation.

TITLE I—PUTTING PATIENTS FIRST BY INCORPORATING THEIR PERSPECTIVES INTO THE REGULATORY PROCESS AND ADDRESSING UNMET NEEDS

SUBTITLE A—PATIENT FOCUSED DRUG DEVELOPMENT

This provision (Section 1001), led by **Health Subcommittee Chairman Joe Pitts (R-PA)** and **Rep. Cathy McMorris Rodgers (R-WA)**, would build off of the Patient Focused Drug Development program at the Food and Drug Administration (FDA). Because no one understands a particular condition or disease better than patients living with it, FDA would be required to establish a structured framework for the meaningful incorporation of patient experience data into the regulatory decision-making process, including the assessment of desired benefits and tolerable risks associated with new treatments.

SUBTITLE B—SURROGATE ENDPOINT QUALIFICATION AND UTILIZATION

This provision (Sections 1021-1024), led by **Rep. Cathy McMorris Rodgers (R-WA)**, would establish a predictable, transparent process for FDA’s consideration, and possible qualification, of surrogate endpoints. The provision also would allow FDA to use private-public partnerships to qualify other types of biomarkers.

SUBTITLE C—APPROVAL OF BREAKTHROUGH THERAPIES

Section 1041, led by **Rep. Michael C. Burgess, M.D. (R-TX)**, would clarify that FDA may approve a drug that has received a breakthrough therapy designation under Section 506(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) when early stage clinical data provides sufficient evidence under the current safety and efficacy standards, considering the risks and benefits of the drug and the risks associated with the disease or condition for which unmet medical needs exist.

SUBTITLE D—ANTIBIOTIC DRUG DEVELOPMENT

The Antibiotic Development to Advance Patient Treatment (ADAPT) Act (Sections 1061-1062), authored by **Reps. John Shimkus (R-IL), Gene Green (D-TX), Diana DeGette (D-CO), Ed Whitfield (R-KY), Anna Eshoo (D-CA), Morgan Griffith (R-VA), Eliot Engel (D-NY), Full Committee Vice Chair Marsha Blackburn (R-TN), and G.K. Butterfield (D-NC)**, would help foster the development of new antibiotics by supporting greater collaboration between industry and FDA around adaptive clinical trials and labeling changes.

Section 1063 would create a new transferable exclusivity program in order to spur additional investment in the area.

The President’s Council of Advisory on Science and Technology has recommended both of these proposals to help support the type of robust drug development that will be needed to ensure patients are protected from bacterial resistance.¹

Section 1064, led by **Reps. Peter Roskam (R-IL) and Danny Davis (D-IL)**, is the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act, which

¹ President’s Council of Advisors on Science and Technology: Report to the President on Combating Antibiotic Resistance, Executive Office of the President, September 2014.

would incentivize new drug development by improving the process of hospital payments for purposes of encouraging new drug development of antibiotic drugs for unmet medical needs.

SUBTITLE E—PRIORITY REVIEW FOR BREAKTHROUGH DEVICES

This provision (Sections 1081-1082), led by **Health Subcommittee Chairman Joe Pitts (R-PA)**, would establish a process at FDA for the designation and expedited review of devices that represent breakthrough technologies with the potential to address unmet medical needs. If FDA designates a medical device as such under Section 1161 and approves/clears it, Section 1162 would translate into Medicare and Medicaid transitional coverage benefits. As this policy is still under development, Section 1162 currently contains a placeholder.

SUBTITLE F—ACCELERATED APPROVAL FOR BREAKTHROUGH DEVICES

This provision (Section 1101) would establish an accelerated approval pathway for medical devices, similar to the pathway that currently exists for drugs.

SUBTITLE G—EXPANDED ACCESS

These sections (1121-1125), led by **Reps. Michael McCaul (R-TX) and Michael C. Burgess, M.D. (R-TX)**, are based on the Expanded Access Improvement Act and would place transparency requirements on certain drug companies regarding their expanded access programs (programs for patients to access drugs before they are approved). It also would create an expanded access task force to provide recommendations to Congress for further reforms of the program.

SUBTITLE H—FACILITATING RESPONSIBLE COMMUNICATION OF SCIENTIFIC AND MEDICAL DEVELOPMENTS

FDA's current rules and policies governing what drug and device developers may say about their own products were designed decades ago. Since then, the way that medicine is practiced and delivered and the way that information is communicated have fundamentally changed. Section 1141 includes placeholder language because the committee is working on a proposal that would clarify and rationalize these rules of the road so that scientific and medical developments can be shared with physicians, insurers, and researchers, with appropriate safeguards, in order to optimize patient care.

SUBTITLE I—MODERNIZING THE REGULATION OF SOCIAL MEDIA

This provision (Section 1161), led by **Rep. Billy Long (R-MO)**, would provide more certainty regarding the regulations of communications on social media by FDA.

SUBTITLE J—STREAMLINED DATA REVIEW

The provision (Section 1181) led by **Rep. Michael C. Burgess, M.D. (R-TX)**, would streamline the review process for adding indications to a drug label by allowing FDA to accept and review data summaries rather than full data packages.

SUBTITLE K—CURES ACCELERATION NETWORK

Section 1201 would provide the National Center for Advancing Translational Science (NCATS) of the National Institutes of Health (NIH) with more flexibility on the use and funding of Other Transaction Authority (OTA) so it can operate even more like the Defense Advanced Research Projects Agency (DARPA).

Section 1202 would authorize additional funds for research on repurposing drugs for new uses. One of NCATS' projects involves finding new uses for old drugs (i.e., using a drug for cancer for a rare disease). Because these old drugs have no more patent life and generics have entered the market, there is little economic reason for a brand or generic manufacturer to conduct this research. To advance the science around repurposed drugs, this provision would authorize additional funding for NCATS.

SUBTITLE L—DORMANT THERAPIES

The provision (Sections 1221-1223) was introduced by **Senators Orrin Hatch (R-UT) and Michael Bennet (D-CO)** in December 2014 and is based on the MODDERN Cures Act, which has been spearheaded in the House by **Rep. Leonard Lance (R-NJ) and supported by 48 Republicans and 47 Democrats**.

The time and expense to develop therapies for complex diseases, such as Alzheimer's, pose unique challenges that make it harder to bring treatments and cures to market. In many ways, the current framework rewards companies for researching and developing treatments where development is relatively easier and faster, and it discourages investment in therapies for scientifically complex and rare diseases. The Dormant Therapies Act would address this issue by rewarding investment in treatments and cures for patients where there are unmet medical needs. It would allow innovators to choose a new pathway and receive a fixed year protection period for these therapies upon FDA approval. This change would shift research and development towards therapies based on scientific promise and patient need, rather than patent life. It also would reward investment in treatments and cures for complex diseases where it takes longer to develop safe and effective therapeutics.

SUBTITLE M—NEW THERAPEUTIC ENTITIES

The New Therapeutic Entities Act (Section 1241), led by **Rep. Gus Bilirakis (R-FL)**, would extend exclusivity for two years for significant improvements to existing molecules under Section 505(b)(2) of the FDCA. These improvements could include developing new delivery systems, new drug combinations, and new formulations that lead to less adverse events and increase patient benefits and adherence.

SUBTITLE N—ORPHAN PRODUCT EXTENSIONS NOW

This Orphan Drug Extension Act (Section 1261), led by **Reps. Gus Bilirakis (R-FL) and G.K. Butterfield (D-NC)**, would provide six months of additional market exclusivity for a drug if the company establishes that the drug treats a rare disease and receives a rare disease indication from the FDA on its label.

TITLE II—BUILDING THE FOUNDATION FOR 21ST CENTURY MEDICINE, INCLUDING HELPING YOUNG SCIENTISTS

SUBTITLE A—21ST CENTURY CURES CONSORTIUM ACT

This provision (Section 2001), led by **Rep. Cathy McMorris Rodgers (R-WA)**, would establish a public-private partnership to accelerate the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients. It would be led by a board composed of government leaders from NIH, FDA, and CMS and leaders from medical device companies, pharmaceutical companies, academic research institutions, patient groups, health plans, and others. While this Consortium is broader in scope, it is based on the success of the European Union’s Innovative Medicines Initiative.

SUBTITLE B—MEDICAL PRODUCT INNOVATION ADVISORY COMMISSION

This provision (Section 2021) would create the Medical Product Innovation Advisory Commission. This Commission, which is based on MedPAC, would advise Congress on issues related to the discovery-development-delivery cycle.

SUBTITLE C—REGENERATIVE MEDICINE

This provision (Section 2041) would require FDA to update its guidance on surrogate and intermediate endpoints for the accelerated approval of regenerative medicine products.

SUBTITLE D – GENETICALLY TARGETED PLATFORM TECHNOLOGIES FOR RARE DISEASES

This provision (Section 2051) would clarify the accelerated approval pathway to enable FDA to rely on data from products that utilize similar genetically targeted platform technology.

SUBTITLE E—SENSIBLE OVERSIGHT FOR TECHNOLOGY WHICH ADVANCES REGULATORY EFFICIENCY (SOFTWARE)

This provision (Sections 2061-2063), includes language from the recently released discussion draft based on H.R. 3303, the SOFTWARE Act, which was introduced by **Full Committee Vice Chair Marsha Blackburn (R-TN), Health Subcommittee Ranking Member Gene Green (D-TX) and Reps. Greg Walden (R-OR), Diana DeGette (D-CO), and G.K. Butterfield (D-NC)**. The language would help provide regulatory certainty for those developing apps and health information technologies.

SUBTITLE F—BUILDING A 21ST CENTURY DATA SHARING FRAMEWORK

These sections (Sections 2081, 2082, 2085, 2086, 2087, 2088, 2091, and 2092), led by **Reps. Morgan Griffith (R-VA), Leonard Lance (R-NJ), and Larry Bucshon, M.D. (R-IN)**, would establish a data sharing framework to enable (1) patients and physicians to better identify ongoing clinical trials, thereby increasing opportunities for patients in need of a treatment, (2) researchers and developers to use Medicare data for the purposes of improving the quality of patient care, and (3) a process for Congress to address other issues identified by the President's Council of Advisors on Science and Technology so that data can continue to fuel all areas of the 21st Century Cures cycle.²

SUBTITLE G—UTILIZING REAL-WORLD EVIDENCE

This provision (Section 2101), led by **Rep. Michael C. Burgess, M.D. (R-TX)**, would authorize FDA to utilize real world evidence and require FDA to issue guidance on collecting such evidence.

SUBTITLE H—COVERAGE WITH EVIDENCE DEVELOPMENT

The provision (Section 2121), led by **Rep. John Shimkus (R-IL)**, would address the long and sometimes costly process that new technology developers must go through to secure CMS coverage, while reducing seniors medical costs by allowing for Medicare beneficiaries to secure coverage from the program for products that are the subject of the clinical trial in which they participate.

SUBTITLE I—COMBINATION PRODUCTS

Sections 2141-2142, led by **Rep. Gus Bilirakis (R-FL)**, would require FDA to set forth additional guidance on the review process for products that include both drugs and devices.

SUBTITLE J—MODERNIZING REGULATION OF DIAGNOSTICS

This provision (Section 2161) includes placeholder language.

SUBTITLE K—INTEROPERABILITY

This provision (Section 2181) includes placeholder language as **Rep. Michael C. Burgess, M.D. (R-TX)** continues to work toward the goal of a national interoperable health information infrastructure.

SUBTITLE L—NIH – FEDERAL DATA SHARING

This provision (Section 2201), led by **Health Subcommittee Chairman Joe Pitts (R-PA)**, would require those receiving NIH grants to share their data, subject to confidentiality and trade secret protections.

² President's Council of Advisors on Science and Technology: Report to the President: Big Data and Privacy: A Technological Perspective, Executive Office of the President, May 2014

SUBTITLE M—ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES

Section 2221 would unlock the research potential of data siloed in health care facilities across the country and enable patients who want to play a more proactive role in finding better treatments or a cure for their disease to do so in a responsible manner that continues to protect their privacy.

SUBTITLE N—21ST CENTURY CHRONIC DISEASE INITIATIVE ACT

This provision (Section 2241) would require the Secretary of Health and Human Services (HHS) to develop a plan to carry out a longitudinal study designed to improve the outcomes of patients with chronic disease.

SUBTITLE O—HELPING YOUNG EMERGING SCIENTISTS

These sections (2261-2262), authored by **Rep. Andy Harris (R-MD)**, would establish a program at NIH to help young emerging scientists.

SUBTITLE P—FOSTERING HIGH-RISK, HIGH-REWARD SCIENCE

This provision (Section 2281), led by **Rep. Andy Harris (R-MD)**, would require NIH to support projects that pursue innovative approaches to major challenges in biomedical research that are high-risk, but have the potential to lead to breakthroughs.

SUBTITLE Q—PRECISION MEDICINE

This provision (Section 2301) includes placeholder language.

TITLE III—MODERNIZING CLINICAL TRIALS

SUBTITLE A—CLINICAL RESEARCH MODERNIZATION ACT

This provision (Section 3001-3002), led by **Reps. Cathy McMorris Rodgers (R-WA) and Diana DeGette (D-CO)**, would help streamline the institutional review board (IRB) process, particularly for clinical trials conducted at multiple sites, by minimizing regulatory duplication and unnecessary delays.

SUBTITLE B—BROADER APPLICATION OF BAYESIAN STATISTICS AND ADAPTIVE TRIAL DESIGNS

This provision (Section 3021), led by **Rep. Chris Collins (R-NY)**, would encourage the broader application of Bayesian statistics and adaptive trial designs.

SUBTITLE C—POST-APPROVAL STUDIES AND CLINICAL TRIALS

This provision (Section 3031), sponsored by **Rep. Chris Collins (R-NY)**, would ensure that FDA and sponsors periodically evaluate whether post-approval studies remain scientifically warranted.

SUBTITLE D—PEDIATRIC RESEARCH NETWORK IMPROVEMENT

This provision (Section 3041), led by **Rep. Cathy McMorris Rodgers (R-WA)**, would require NIH to implement the National Pediatric Research Network Act, which was established as part of the PREEMIE Reauthorization Act (P.L. 113-55).

SUBTITLE E—GLOBAL PEDIATRIC CLINICAL TRIAL

This provision (Section 3061), led by **Health Subcommittee Chairman Joe Pitts (R-PA)**, would set forth a Sense of Congress that NIH and FDA should work with European Union, industry, and others to establish a global pediatric clinical trial network.

TITLE IV—ACCELERATING THE DISCOVERY, DEVELOPMENT, AND DELIVERY CYCLE AND CONTINUING 21ST CENTURY INNOVATION AT NIH, FDA, CDC, AND CMS

SUBTITLE A—NATIONAL INSTITUTES OF HEALTH

Section 4001 – NIH research strategic investment plan

Section 4001, based on the work of **Rep. Andy Harris (R-MD)**, would require NIH to issue a strategic plan.

Section 4002 – Biomedical research working group to reduce administrative burden on researchers

Section 4002, led by **Rep. Andy Harris (R-MD)**, would establish a working group composed of NIH and stakeholders to provide recommendations on how to streamline the grant process for researchers.

Section 4003 – NIH travel

Section 4003 contains a placeholder.

Section 4004 – Increasing accountability at the National Institutes of Health

Section 4004, based on the work of **Chairman Emeritus Joe Barton (R-TX)** and **Rep. Andy Harris (R-MD)**, would provide the NIH Director with more authority over the institutes and centers at NIH.

Section 4005 – GAO report on Common Fund

Section 4005, authored by **Chairman Emeritus Joe Barton (R-TX)**, would require the Government Accountability Office to conduct a study on the NIH's Common Fund.

Section 4006 – Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements

Section 4006, led by **Rep. Leonard Lance (R-NJ)**, would exempt certain NIH research activities from the Paperwork Reduction Act.

Section 4007 – Additional Funding for NIH Common Fund

Section 4007 would authorize additional funding for the NIH Common Fund.

Section 4008 – Additional Funding for NIH Brain Research

Section 4008, based on the work of **Rep. Tim Murphy (R-PA)**, would authorize funding for the NIH's BRAIN initiative.

Section 4009 – NCATS Phase IIB Restriction

Section 4009 would remove NCATS' phase IIB clinical trial funding restriction.

SUBTITLE B—ADVANCING RESEARCH FOR NEUROLOGICAL DISEASES

This provision (Section 4021), led by **Reps. Michael C. Burgess, M.D. (R-TX) and Chris Van Hollen (D-MD)**, would require the Centers for Disease Control and Prevention (CDC) to set up a surveillance system for neurological diseases.

SUBTITLE C—VACCINE ACCESS, CERTAINTY, AND INNOVATION

These provisions (Sections 4041- 4048, 4061-4063), led by **Rep. Renee Ellmers (R-NC)**, would provide certainty and transparency with respect to the regulation of vaccines, including with respect to CDC and CMS.

SUBTITLE D – REAGAN-UDALL IMPROVEMENTS

This provision (Section 4081), led by **Full Committee Vice Chair Marsha Blackburn (R-TN)**, would improve the Reagan-Udall Foundation.

SUBTITLE E—FDA HIRING, TRAVEL, AND TRAINING

This provision (Section 4101) contains placeholder language.

SUBTITLE F—FDA SUCCESSION PLANNING

These provisions (Sections 4121-4122), led by **Health Subcommittee Vice Chair Brett Guthrie (R-KY)**, would ensure that FDA staff has the ability to continue to improve their expertise and that FDA develops a succession plan for management positions.

SUBTITLE G—DISPOSABLE MEDICAL TECHNOLOGIES

This provision (Section 4141), led by **Rep. Renee Ellmers (R-NC)**, would reform the coverage requirements under the Medicare program for certain disposable medical technologies.

SUBTITLE H—LOCAL AND NATIONAL COVERAGE DECISION REFORMS

This provision (Section 4161), led by **Health Subcommittee Vice Chair Brett Guthrie (R-KY)**, would reform the Medicare local coverage determination (LCD) process. It also includes a request for additional ideas.

SUBTITLE I—TELEMEDICINE

This provision (Section 4181), led by **Health Subcommittee Chairman Joe Pitts (R-PA), Full Committee Ranking Member Frank Pallone (D-NJ) and Reps. Gregg Harper (R-MS), Doris Matsui (D-CA), Bill Johnson (R-OH), Peter Welch (D-VT), Greg Walden (R-OR), and Bob Latta (R-OH)**, would advance opportunities for telemedicine and new technologies to improve the delivery of quality health care services to Medicare beneficiaries.

SUBTITLE J—REVISE IPPS NEW TECHNOLOGY ADD-ON PAYMENT (NTAP) REIMBURSEMENT AMOUNTS

This provision (Section 4201) would provide more transparency regarding the new technology add-on payment (NTAP) reimbursement process.

SUBTITLE K—LOWERING MEDICARE PATIENTS OOP COSTS

This provision (Section 4221), led by **Rep. Gus Bilirakis (R-FL)**, would allow seniors to better identify the out of pocket costs they might face for a given treatment or service and pick the service that is right for them and their budget.

SUBTITLE L—GLOBAL SURGERY SERVICES RULE

This provision (Section 4241), led by **Rep. Larry Bucshon, M.D. (R-IN)**, would prevent the implementation of the global surgery services rule, which does away with bundled payments for surgeons.

SUBTITLE M—PROVIDERS CONSOLIDATION AND MEDICARE PAYMENTS EXAMINED THROUGH EVALUATION

This provision (Section 4261), led by **Rep. Michael C. Burgess, M.D. (R-TX)**, would require CMS to analyze and seek public input on how proposed Medicare payment policies would affect the consolidation of providers and payers.

SUBTITLE N—MEDICARE PART D PATIENT SAFETY AND DRUG ABUSE PREVENTION

This provision (Sections 4281-4284), led by **Reps. Gus Bilirakis (R-FL), Ed Whitfield (R-KY), Billy Long (R-MO) and Ben Ray Lujan (D-NM)**, would help prevent high-risk Medicare beneficiaries from abusing controlled substances.

SUBTITLE O—ACCELERATING INNOVATION IN MEDICINE

This provision (Section 4301), led by **Rep. Erik Paulsen (R-MN)**, would establish a program that allows for patients to access medical device treatments sooner than otherwise would be available.

SUBTITLE P—MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN

This provision (Section 4321), led by **Rep. Susan Brooks (R-IN)**, would establish an ombudsman at CMS to allow medical device and pharmaceutical companies to appeal decisions and better understand the reasoning behind Medicare coverage decisions.

SUBTITLE Q—ENSURING LOCAL MEDICARE ADMINISTRATIVE CONTRACTORS EVALUATE DATA RELATED TO CATEGORY III CODES

This provision (Section 4341) would ensure that local Medicare Administrative Contractors review all data before making coverage decisions on Category III codes.

SUBTITLE R—ADVANCING CARE FOR EXCEPTIONAL KIDS

This provision (Sections 4361-4362), led by **Chairman Emeritus Joe Barton (R-TX) and Rep. Kathy Castor (D-FL)**, would establish a Medicaid and CHIP Care Coordination program for children with medically complex conditions.

SUBTITLE S—CONTINUING MEDICAL EDUCATION SUNSHINE EXEMPTION

This provision (Section 4381), based on H.R. 293, which was introduced by **Reps. Michael C. Burgess, M.D. (R-TX) and Peter DeFazio (D-OR)** would clarify that peer-reviewed journals, journal reprints, journal supplements, and medical textbooks are excluded from the reporting requirement under the Sunshine Act.

SUBTITLE T—MEDICAL TESTING AVAILABILITY

This provision (Section 4401), based on H.R. 298, which was introduced by **Reps. Michael C. Burgess, M.D. (R-TX) and Jackie Speier (D-CA)**, would clarify the law regarding Research Use Only (RUO) labeled products.

TITLE V—MODERNIZING MEDICAL PRODUCT REGULATION

SUBTITLE A—MANUFACTURING INCENTIVES

This provision (Section 5001), led by **Health Subcommittee Vice Chair Brett Guthrie (R-KY)**, would provide incentives for manufacturing generic drugs here in the U.S.

SUBTITLE B—21ST CENTURY MANUFACTURING

This provision (Section 5021), led by **Health Subcommittee Vice Chair Brett Guthrie (R-KY)**, would require FDA to update its guidance regarding novel manufacturing techniques.

SUBTITLE C—CONTROLLED SUBSTANCE MANUFACTURING AND EXPORTS

This provision (Section 5041), led by **Health Subcommittee Chairman Joe Pitts (R-PA)**, would provide U.S. pharmaceutical companies with a level-playing field regarding controlled substances exports.

SUBTITLE D—MEDICAL DEVICE REFORMS

Section 5061 – Third-party quality system assessment

Section 5061, led by **Rep. John Shimkus (R-IL)**, would allow FDA to rely on third party accredited bodies to certify minor manufacturing changes.

Section 5062 – Valid scientific evidence

Section 5062, led by **Rep. John Shimkus (R-IL)**, would clarify that valid scientific evidence includes well-documented, real world evidence gathered from clinical registries and studies published in peer-reviewed journals.

Section 5063 – Training and oversight in least burdensome means concept

Section 5063, led by **Rep. John Shimkus (R-IL)**, would ensure that FDA reviewers are trained on the least burdensome concept.

Section 5064 – Recognition of standards

Section 5064, authored by **Rep. John Shimkus (R-IL)**, would improve the process of government recognition of appropriate standards set by the medical community.

Section 5065 – Notification of marketing of certain class I devices

Section 5065, led by **Health Subcommittee Vice Chair Brett Guthrie (R-KY)**, would streamline the process of marketing Class I medical devices.

Section 5066 – General and specific uses

Section 5066, led by **Rep. John Shimkus (R-IL)**, would streamline the 510(k) process for medical devices.

Section 5067 – Humanitarian device exemption application to in vitro diagnostics

Section 5067, led by **Rep. Leonard Lance (R-NJ)**, would allow FDA the authority to apply the Humanitarian Device Exemption (HDE) to areas that impact more than 4,000 patients where the public health requires a greater availability to treat or diagnose such patients and there is no alternative.

Section 5068 – Advisory committee process

Section 5068, led by **Rep. John Shimkus (R-IL)**, would streamline the FDA committee advisory process.

SUBTITLE E—SUPPLY CHAIN SECURITY FOR DEVICES

This provision (Sections 5081-5088), led by **Rep. Bob Latta (R-OH)**, would establish a national framework for licensure of medical device wholesalers and third-party logistics providers, similar to what Congress enacted for prescription drugs in the Drug Quality and Security Act (P.L. 113-54).