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February 19, 2015

The Honorable Lamar Alexander
Chairman

Committee on Health, Education, Labor, and Pensions
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr

217 Russell Senate Office Building
Washington, DC 20510

Dear Senators:

On behalf of the Infectious Diseases Society of America (IDSA), I write to thank you for developing the Innovation for Healthier Americans report and providing us with the opportunity to comment upon the issues it raises. IDSA greatly appreciates your leadership in this area as well as the hard work evident in this thoughtful and wide-ranging report. IDSA is committed to federal policies that will promote the research, development and appropriate use of new vaccines, diagnostics and antimicrobial drugs to prevent, detect, and treat infectious diseases, including those caused by multidrug resistant pathogens.

Urgent need for new antibiotics and diagnostics

IDSA remains particularly focused on the development of urgently needed new antibiotics and diagnostics. Antibiotics are generally accepted as the greatest curative development of the 20th century and now credited with a 26-year increase in average longevity. This progress is threatened by the rapid rise of antibiotic resistant bacteria coupled with a persistent market failure to develop new antibiotics. As infectious diseases physicians, we are seeing increasing numbers of patients infected with multidrug resistant pathogens, and we are unable to satisfactorily treat them with our existing arsenal of antibiotics. This Committee has already demonstrated great leadership in addressing this issue, through the passage of the Generating Antibiotic Incentives Now (GAIN) Act in 2012. We look forward to working with the Committee to build upon this important first step.

As you may know, in September 2014, the President's Council of Advisors on Science and Technology (PCAST) issued a report to the President entitled [Combating Antibiotic Resistance](#), which calls for a wide variety of policies to address the economic and regulatory barriers to antibiotic and diagnostics development. Immediately following the PCAST report, the President released a [National Strategy for Combating Antibiotic Resistant Bacteria \(CARB\)](#), which includes key goals of accelerating the development of new antibiotics, diagnostics and vaccines. IDSA is delighted that both the PCAST report and the National Strategy reflect many of the recommendations made by IDSA in our [2004 Bad Bugs, No Drugs report](#) and our [2011 Combating Antimicrobial Resistance: Policy Recommendations to Save Lives report](#).

IDSA's brand new [Better Tests, Better Care: The Promise of Next Generation Diagnostics report](#), released just last month, calls attention to the urgent need for new infectious diseases diagnostic tests that provide rapid results, are easy to use, and accurately identify the pathogen causing an infection and the best antibiotic to use. New and improved diagnostics can significantly improve patient care by giving physicians the information they need to more rapidly provide appropriate treatment. Currently, 20-30% of patients with sepsis receive inadequate initial treatment because the cause of the infection can take several days to diagnose. Better diagnostics can also improve public health by identifying patients for whom isolation or other infection control measures are needed, improving the tracking of outbreaks and emerging infectious diseases threats. Improved diagnostics can also guide the appropriate use of antimicrobial drugs, and therefore are critical to the campaign to address antibiotic resistance. Thanks to advancements in scientific research, promising new diagnostic tools are within reach. But greater investment and improved regulatory policies are needed to ensure that scientific advancements translate into the development and use of new diagnostics.

Below, IDSA is pleased to respond to specific questions raised by the Committee. We hope this feedback will be useful as you develop legislation to advance biomedical innovation for the benefit of patients.

IV. It Takes Too Long and Costs Too Much to Develop Medical Products for American Patients

How are the federal government's actions, including legislation and regulation, and inaction contributing to the challenges that impede timely access to cutting-edge products for too many Americans?

IDSA shares the Committee's concern that economic and regulatory hurdles are impeding research and development (R&D). This is particularly true for new antibiotics. Unlike other types of drugs, the use of antibiotics decreases their effectiveness over time due to the development of resistance by the bacteria that infect us. And companies are lacking sufficient incentives to develop new antibiotics. Antibiotics are typically priced low compared to other new drugs, used for a short duration, and held in reserve to protect their utility, making them far less economically viable investments for companies than other types of drugs. In 1990, there were nearly 20 pharmaceutical companies with large antibiotic research and development (R&D) programs. Today, there are only 2 or 3 large companies with strong and active programs and a few small companies with more limited programs. An [IDSA report](#) issued in April 2013 identified only seven new drugs in the development pipeline for the treatment of serious infections caused by multidrug resistant Gram negative bacilli, too few considering the typically very high attrition rate during the process of antibiotic development.

Over the last few years, Congress and the Administration have taken several important steps to help foster the development of urgently needed antibiotics and antifungals, diagnostics, and vaccines. In 2012, as part of the Food and Drug Administration Safety and Innovation Act (FDASIA), Congress enacted the GAIN Act, which provides an additional five years of exclusivity for new antibiotics that treat a serious or life-threatening infection. This important first step signaled to the pharmaceutical industry that Congress is committed to addressing the

urgent need for new antibiotics. But stakeholders agree that additional incentives are needed. Later in this letter, IDSA is pleased to offer more specific recommendations regarding such incentives.

The National Institute of Allergy and Infectious Diseases (NIAID) recently launched the [Antibacterial Resistance Leadership Group \(ARLG\)](#) to develop, design, implement, and manage a clinical research agenda to increase knowledge of antibacterial resistance. The ARLG is focused on antibacterial drug and diagnostics development, optimal usage strategies, infection control, and activities to limit the development of resistance. This important initiative has the potential to deliver significant results, but limited funding for NIAID in turn limits funding for the ARLG. **As a complement to the Innovations effort, IDSA urges you to work with your colleagues on the Appropriations Committee to ensure robust funding for NIAID.**

IDSA appreciates your leadership establishing and supporting the Biomedical Advanced Research and Development Authority (BARDA) which partners with companies to develop medical countermeasures, including new antibiotics, diagnostics and vaccines, which can address threats to our nation's biosecurity. Through its broad-spectrum antimicrobials project, BARDA is currently supporting some small and large companies' efforts to develop life-saving new antibiotics that may be useful not only in bioemergencies, but also in traditional healthcare settings. Similarly, BARDA is also partnering with device companies to develop new diagnostic tests, with a focus on tests that provide rapid, accurate results and are simple enough to be used at the point of care. Through its influenza division, BARDA supports the advanced development of influenza vaccines and antiviral drugs. Unfortunately, BARDA's funding, which has been flat in recent years, limits the agency's ability to address ever growing needs. Further, medical products must reach a certain stage of development before they become eligible for BARDA assistance, and greater economic and regulatory incentives are needed to encourage companies to begin development of needed products. **As the Committee considers ways to improve access to cutting edge medical products, IDSA urges you to work with your colleagues on the Appropriations Committee to increase funding for BARDA.**

Providing appropriate coverage and reimbursement for urgently needed vaccines, diagnostics and antimicrobial drugs is critical for ensuring patient access to these products. Without sufficient reimbursement, healthcare providers are often unable to appropriately utilize existing tools. Further, companies are often unwilling to invest in the development of products unless they are reasonably confident that the product will be appropriately reimbursed. The federal government has taken some positive steps forward in this area, but much work remains. For example, the current discrepancy between Medicare Part B and Part D coverage of important vaccines is a significant barrier to seniors' access to vaccines. Under current law, Medicare Part D plans are responsible for covering vaccines not covered under Medicare Part B, including those protecting seniors from herpes zoster, whooping cough, tetanus, and diphtheria. Unfortunately, not all seniors have Part D plans, and even those who do are often subject to prohibitively expensive copays for these vaccines. In addition, the existing fractured coverage imposes significant administrative challenges for patients, physicians, and pharmacists. For example, patients who need the herpes zoster vaccine to prevent shingles must obtain the vaccine from a pharmacist but then have it administered by a healthcare provider. This policy leads to fewer seniors receiving this vaccine. **As the Committee advances the Innovations initiative,**

IDSA recommends that you work with your colleagues on the Finance Committee to advance legislation requiring coverage for all Advisory Committee on Immunization Practices (ACIP) recommended vaccines through both Medicare Part B and D to ensure that no senior falls through the cracks.

With regard to diagnostic tests, reimbursement rates that do not even cover the cost of new tests seriously hinder patient access to innovative tests that can provide more rapid results. Shortening test result turnaround times from days to hours or even minutes can significantly speed access to effective treatments, shortening hospital stays and improving patient outcomes. Reimbursement rates must facilitate patient access to innovative diagnostic tests. IDSA is grateful for provisions in the Protecting Access to Medicare Act of 2014 (PAMA) that seek to improve reimbursement for diagnostic tests. Specifically, we look forward to the Centers for Medicare and Medicaid Services (CMS) establishment of an expert advisory panel, as required by PAMA, which will provide input on the development, validation, performance, and application of clinical laboratory tests. Infectious diseases diagnostics face unique issues and have tremendous potential to significantly improve not only individual patient care, but also public health by identifying patients for whom infection control measures must be taken and by guiding appropriate antimicrobial drug use to limit the development of antimicrobial resistance. **IDSA hopes the Committee, in partnership with the Finance Committee, will conduct appropriate oversight to ensure that CMS includes infectious diseases experts in the upcoming advisory panel.**

Lastly, IDSA recognizes that antibiotics are typically priced low, as compared to other classes of drugs, relative to their significant benefit to patients and public health, and low reimbursement is a disincentive to antibiotic R&D. Some companies have sought increased reimbursement for new antibiotics through the New Technology Add-On Payment (NTAP) program. Unfortunately, CMS, which administers this program, has indicated that drugs should provide superiority data in order to be deemed eligible. Superiority trials are often not possible for new antibiotics due to both ethical and practical concerns. First, it is unethical to knowingly administer placebo to patients with serious or life-threatening infections. Second, superiority studies that compare a new, experimental antibiotic to another drug already on the market can be problematic as well. For some infections caused by highly resistant pathogens, there may be no appropriate comparator. Even when a comparator exists, ethical issues still make superiority trials highly problematic in some cases. Third, primary outcomes in clinical trial designs whether superiority or non-inferiority are efficacy based and do not take into account other important factors such as toxicity, adverse events, route or frequency of administration and need for monitoring that can confer meaningful clinical benefit and enhance utility. **IDSA urges the Committee, in partnership with the Finance Committee, to conduct appropriate oversight of the NTAP program to help ensure that new antibiotics are appropriately evaluated.** Recently, the FDA has demonstrated increased willingness to consider approval of new antibiotics of proven efficacy and shown to have achieved well-defined and statistically validated non-inferiority margins. IDSA has encouraged CMS to take a similar approach when determining whether a new antibiotic should receive NTAP. We also urged CMS to consider carefully analyzed and peer-reviewed safety, utilization and economics data when such data are available to support an NTAP payment for a new antibiotic. This could increase the types of information that would be considered for drugs for which superiority trials are inappropriate

and/or not feasible. **In addition, given that NTAP has thus far not been appropriately utilized for antibiotics, the Committee should consider legislation that would specifically improve reimbursement for new antibiotics, such as Sec. 1064 of the House Energy and Commerce Committee’s 21st Century Cures discussion draft. In order to appropriately target limited federal resources, IDSA recommends that such legislation be applied to new antimicrobial drugs that treat a serious or life-threatening infection and address an unmet medical need.**

What resources have been spent, and where? How can limited resources be utilized in the most efficient manner, what are the most opportune strategic initiatives and how do they get decided?

In our response to the above question, IDSA noted key investments through NIAID and BARDA for antimicrobial drug, diagnostics and vaccine development. With regard to the specific question of utilizing resources in the most efficient manner, IDSA would like to highlight a specific project of the NIAID-funded Antibacterial Resistance Leadership Group (ARLG)—a virtual biorepository. A key challenge in clinical trials for new diagnostics is access to clinical samples, particularly those containing rare pathogens. Many clinical laboratories no longer freeze specimens containing novel or unusual organisms for further use. Even when such critical samples are available, the cost of accessing them has, in many cases, become prohibitive. The ARLG established a [Virtual Biorepository \(VB\) Catalogue](#), a web-based system run by the Duke Clinical Research Institute that provides researchers with unique access to clinically well-characterized bacteria for the development of diagnostic tests and other research. The bacteria are already being collected through other ARLG research projects and are housed at multiple locations. This approach requires significantly fewer resources than traditional physically centralized biorepositories. Researchers are able to search the virtual biorepository catalogue to locate the samples they need. This approach could be very useful in other areas of infectious diseases diagnostics development (e.g., samples of viruses, fungi, etc.). **As the Committee develops legislation for the Innovations effort, IDSA urges you to include a provision directing NIAID to examine opportunities to support the development of virtual biorepositories for viruses, fungi and other pathogens, utilizing samples already being collected under existing NIAID-funded research, similar to the existing bacteria virtual biorepository. Attached, IDSA is pleased to provide draft legislative language for the Committee’s consideration. We also encourage the Committee to provide incentives and support for institutions to save de-identified specimens and to participate in virtual biorepository catalogues when possible.**

IDSA also believes that public private partnerships (PPP) are a very important tool for leveraging limited resources to provide the maximum benefit for patients. In the area of infectious diseases, BARDA has been a strong and necessary public partner for companies to develop urgently needed antibiotics, diagnostics, and influenza vaccines and antivirals, as discussed above. However, the BARDA model to date has been limited—primarily structured to allow BARDA to partner with individual companies for product development. The U.S. lacks a forum that can convene multiple companies, academic researchers and other expert stakeholders to work collaboratively to address the scientific challenges facing the research and development of novel vaccines, diagnostics and therapeutics. **The European Union’s Innovative Medicine’s**

Initiative (IMI) provides exactly this type of forum, and IDSA strongly recommends the development of a complementary effort in the U.S. Below are examples of how the IMI has been particularly useful in the development of new infectious diseases diagnostics and new antibiotics.

In 2011, the European Commission (EC) launched the Rapid Point-of-care test Platforms for Infectious Diseases (RAPP-ID) project, a PPP bringing together government experts, academia and industry, which aims to develop fast and reliable point-of-care tests for the detection of various pathogens. RAPP-ID is gathering input from clinicians to focus its activities on areas of greatest need that can most significantly impact patient care. This effort is focused on diagnostics for bloodstream infections, lower respiratory tract infections (including community-acquired pneumonia and ventilator-associated pneumonia) and tuberculosis. Collaborative approaches like RAPP-ID are critical for addressing some of the key hurdles to diagnostics R&D, including access to clinical specimens and laboratory expertise, as well as scientific challenges.

In 2012, the EC launched the New Drugs for Bad Bugs (ND4BB) public private partnership. PPPs are essential to furthering the discovery process for new antibiotics because they convene the required diverse stakeholders to tackle the complex scientific and economic challenges facing antibiotic R&D. For example, ND4BB brings together government leaders, academia, industry and other experts for an unprecedented sharing of information and multi-disciplinary collaboration. The focus of the overall program is to develop better networks of researchers, create fluid and innovative clinical trial designs and provide incentives for companies to meet the challenges of antibiotic resistance quickly and efficiently. Initial funding for ND4BB (approximately \$300 million for the first phase) was nearly equally split between government and industry sources.

Title II, Subtitle A of the House Energy and Commerce Committee's 21st Century Cures discussion draft seeks to establish such an entity. IDSA was pleased to see this provision included in the discussion draft; however, we offered comments requesting that diagnostics be included and that grants be provided to partnerships that include academic groups, informatics groups, and large and small companies. Multiple IDSA leaders have been engaged with the IMI's activities, and we are pleased to offer their expertise as the Committee crafts legislation.

V. From Bench to Bedside: The Role of Basic Research in New Medical Products

As we study “whole pathways, organ systems, or even entire organisms rather than limiting the research to a single aspect of cell biology or physiology,” are our research institutions similarly changing to reach across those respective research missions in order to coordinate research agendas, leverage resources, and facilitate scientific discovery?

America's research institutions are working tirelessly to lead the way in innovative approaches and scientific advancements. However, federal policies are posing significant challenges. First, the overall climate of fiscal austerity and specifically the policy of budget sequestration do not facilitate a strong commitment to biomedical research. As the Committee has noted, NIH

purchasing power has declined in recent years, and the impact of that decrease is felt across the board by researchers and institutions that rely upon federal funding to support their work. When federal funding is decreased or otherwise unstable, researchers are often forced to scale back projects, lay off staff, and abandon some projects entirely. Even when funding returns, it takes significant time for institutions to rebuild necessary infrastructure, causing delays in research that ultimately delay the delivery of innovations to patients. Further, lack of robust, stable funding for NIH is causing many young people to decline pursuing careers in research—an extremely worrisome trend. **IDSA urges the Committee to work with your colleagues on the Appropriations Committee to provide strong, stable funding for the NIH.**

Conflict of interest (COI) policies also unfortunately hamper researchers at many institutions and negatively impact pharmaceutical and medical device companies as well. With respect to diagnostics, for example, expert input or independent validation of a potential test is often needed during development. Companies may wish to get early feedback from physicians about what features of a new diagnostic test would be most helpful in providing optimal patient care, or utilize an expert laboratory to validate tests in development. Institutional COI policies are often much more strict than the NIH [COI regulatory framework](#), which was intended to provide guidance to institutions on how to manage COI. Unfortunately, institutional COI policies often bar those best suited for these activities from engaging with industry in any way, sometimes even if the expert is willing to work for free on his or her own time. Even when an institution does not explicitly ban such activities, policies are sometimes misinterpreted, resulting in a stifling of collaboration between academic researchers and industry. This forces developers to forgo expert input or use laboratories lacking expertise for independent testing. This loss of expert input and the resources diverted to train and supervise testing at laboratories lacking expertise can add considerable time and cost to diagnostics development. **IDSA encourages the Committee to clarify that institutions receiving federal funding should implement COI policies that appropriately enable transparent industry/institutional research collaborations. IDSA is pleased to offer draft legislative language, attached, for your consideration.**

Are there specific existing regulations, policies, or statutes that are impeding the ability of the NIH to support ground-breaking research? Are additional authorities necessary to help the NIH achieve this objective?

As mentioned above, lack of robust, stable NIH funding is significantly impeding NIH's ability to not only support ground-breaking research today, but also to encourage and foster the training of America's next generation of scientists. In addition, institutional COI policies that are much more strict than the NIH COI regulatory framework are barring some of our nation's leading scientific experts from lending their expertise in support of the development of new medical products, as discussed above. This is particularly worrisome for experts on certain rare infectious diseases, as it may not be possible to locate an individual with the appropriate expertise who is not bound by an overly strict COI policy at his or her institution. **IDSA encourages the Committee to clarify that institutions receiving federal funding should implement COI policies that appropriately enable transparent industry/institutional research collaborations. As previously noted, draft legislative language is attached for your consideration.**

How can we improve the appropriate sharing of data and information and enhance the impact of our biomedical research dollars?

As discussed above, public private partnerships that foster true collaboration—including sharing of data and information—among pharmaceutical and device companies, academic researchers, government experts, and other stakeholders, are a crucial tool for enhancing the impact of our biomedical research dollars. **Unfortunately, the U.S. lacks a forum like Europe’s Innovative Medicines Initiative (IMI) to facilitate this type of collaboration. IDSA strongly encourages the Committee to establish a complementary effort in the U.S.**

Also discussed above, virtual biorepositories can be very useful for facilitating the sharing of clinical specimens needed to develop new infectious diseases diagnostic tests. Virtual biorepositories allow specimens to remain stored at the institution at which they are collected, and searchable through an online database, and as such are much more cost effective than traditional centralized physical biorepositories. Further, allowing accessibility to already-collected specimens significantly reduces the burdens associated with repeatedly collecting duplicative specimens. The NIAID, through the Antibacterial Resistance Leadership Group, is already supporting a virtual biorepository for resistant bacterial specimens, and **IDSA strongly recommends that the Committee direct NIAID to look for opportunities to develop a virtual biorepository for other pathogens, including viruses and fungi. As previously noted, draft legislative language is attached for your consideration. We also encourage the Committee to provide incentives and support for institutions to save de-identified specimens and to participate in virtual biorepository catalogues when possible.**

There is also a significant need for information to be collected and shared after a new medical product is developed in order to ensure it is being used appropriately to facilitate optimal patient care. For example, many physicians and other health care providers may be hesitant to use new infectious diseases diagnostic tests, in part because they are often uncertain of how best to integrate them in their practice and how to interpret results. Physicians often look to education, such as clinical guidelines developed by their professional societies, such as IDSA, and government bodies, such as the Agency for Healthcare Research and Quality (AHRQ), to suggest the best methods to diagnose and treat an infection. Little guidance currently exists on the use of diagnostic tests for a particular type of infection, or what bundles of tests should be used if a patient has a particular set of symptoms. The ability to construct useful guidelines is hampered by the lack of clearly designed outcomes studies demonstrating patient benefit when tests are used as part of clinical decision making. **IDSA urges the Committee to direct AHRQ, specifically through its Center for Evidence and Practice Improvement (CEPI), to conduct or support research to demonstrate the impact of new ID diagnostics on patient care and outcomes, and to disseminate the results of that research to physicians to encourage them to appropriately utilize new diagnostics.** IDSA is open to this type of research being conducted or supported elsewhere in the federal government. However, CEPI is well-suited to address this need, as the Center is tasked with conducting and supporting research on health care delivery and improvement and advancing decision and communication sciences to facilitate informed treatment and health care decision making by patients and their health care providers.

VI. Opportunities to Improve Clinical Trials

What's driving the increased time and cost of clinical trials? What are NIH and FDA currently doing to address these issues? Are these efforts effective?

Clinical trials for new antibiotics to treat serious or life-threatening infections and address unmet medical needs face significant and unique obstacles. Some of the most dangerous pathogens are to date occurring in relatively small numbers of patients, making it difficult and sometimes impossible to populate traditional, large scale clinical trials. It is important to develop drugs to treat infections caused by these deadly pathogens before they infect larger numbers of people. Moreover, when a pathogen is resistant to all approved antibiotics, there is no effective antibiotic against which to compare the new antibiotic, which is the standard procedure for clinical trials. Compounding the problem is the lack of rapid diagnostic tests to identify patients infected with certain pathogens who may be eligible for antibiotic clinical trials.

The bipartisan **Promise for Antibiotics and Therapeutics for Health (PATH) Act, S. 185**, introduced by Senators Hatch and Bennet, would allow new antibiotics that treat a serious or life-threatening infection and address an unmet medical need to be studied in smaller clinical trials and approved for a limited population. This approach was recommended by the President's Council of Advisors on Science and Technology (PCAST) in their 2014 Report on Combating Antibiotic Resistance. [Nearly 40 organizations](#) have expressed support for the PATH Act. Similar legislation introduced in the House of Representatives last Congress (the Antibiotic Development to Advance Patient Treatment, or ADAPT, Act) boasted half of the Energy and Commerce Committee as cosponsors and was included in the Committee's 21st Century Cures first discussion draft, Sec. 1061.

Importantly, the PATH Act contains several provisions designed to guide the appropriate use of new antibiotics approved under the new pathway. Appropriate use is critical to deliver optimal patient care and protect these precious drugs from the development of resistance. Key provisions in the PATH Act include clear labeling of drugs approved under this pathway (through a logo or other such means), Food and Drug Administration (FDA) pre-review of marketing materials, and monitoring the use of drugs approved under this pathway, as well as patterns of resistance. **IDSA strongly supports the PATH Act and urges the Committee to advance this critical legislation as part of the Innovations effort.**

New rapid infectious diseases diagnostics are urgently needed for multiple reasons, including helping to identify patients eligible for antimicrobial drug clinical trials. Unfortunately, numerous challenges, including access to clinical specimens and access to appropriate experts, significantly increase the time and cost of diagnostics clinical trials. As discussed above, the existing bacteria virtual biorepository, supported by NIAID through the Antibacterial Resistance Leadership Group, is an innovative approach to easing access to needed specimens and reducing costly, time consuming and duplicative specimen collection. **IDSA urges the Committee to direct NIAID to explore opportunities to develop virtual biorepositories for other pathogens, such as viruses and fungi. Proposed language is attached for your consideration.**

Also noted above, institutional conflict of interest (COI) policies that are considerably stricter than the NIH framework intended to guide COI policies are often barring the most appropriate experts from collaborating in any way with diagnostics developers. Such policies cause multiple problems, including severely limiting the number of laboratories available to help test and validate new diagnostics. Companies are often forced to turn to laboratories that lack sufficient expertise and must then invest significant time and resources for training, which drives up the length and cost of clinical trials. **IDSA urges the Committee to clarify that institutions should adopt COI policies that allow for appropriate collaboration between industry and researchers, as intended by the NIH. Proposed language is attached for your consideration.**

What could NIH and FDA do to address more effectively the challenges associated with clinical trials, including cutting down the time and expense of such trials?

As discussed above, the Antibacterial Resistance Leadership Group (ARLG), supported by NIAID, is a strategic research team that is building transformational trials that will change clinical practice and reduce the impact of antibacterial resistance. ARLG projects focus on the following areas: early clinical evaluation of new antibacterials; comparative effectiveness or efficacy trials; strategy trials to optimize currently licensed antibacterials (dose, duration, need for drug) to reduce the risk of resistance; treatment-based prevention measures; diagnostics testing in the context of treatment trials; effective infection control programs which include surveillance for resistant organisms; outbreak investigation; antibiotic stewardship to prevent the development and spread of resistant organisms; and novel facilities-level activities to prevent the development of resistance. This is an incredibly important effort worthy of greater investment. **We urge you to work with your colleagues on the Appropriations Committee to strengthen funding for NIAID so that the Institute may increase support for the ARLG and other important research activities.**

One aspect of the ARLG that is particularly beneficial for diagnostics clinical trials is its virtual biorepository, which allows researchers to access specimens previously collected for other studies. **As previously mentioned, IDSA urges the Committee to direct NIAID to explore opportunities to establish virtual biorepositories for other types of pathogens, such as viruses and fungi and provides suggested language for your consideration.**

Also noted above, institutional conflict of interest (COI) policies that are significantly more stringent than the NIH COI framework often completely bar key experts from collaborating with industry, including diagnostics developers. Lack of access to key experts is a key barrier to diagnostics clinical trials. **Further clarification from the NIH and Congress that institutional COI policies should not bar all interaction between academic researchers and industry would be very helpful in addressing this problem. Proposed language is attached for your consideration.**

How can Congress remove barriers and facilitate innovation in the administration and design of clinical trials to reduce the time and resources it currently takes to conduct these trials?

As discussed above, the bipartisan PATH Act, S.185, would make trials for new antibiotics that treat a serious or life-threatening infection and address an unmet medical need feasible, more rapid, and less expensive. PATH would allow such antibiotics to be approved for a limited population based upon smaller clinical trials, due to the limited number of patients in whom the targeted infections currently occur. **IDSA strongly urges the HELP Committee to advance the PATH Act as part of the Innovations effort.** Without this approach, it is likely that the antibiotics that patients most urgently need will not be developed.

Congress can also help remove barriers to clinical trials for urgently needed new infectious diseases diagnostics. Key challenges in this area include access to clinical specimens and access to appropriate experts. As discussed above, the existing bacteria virtual biorepository, supported by NIAID through the Antibacterial Resistance Leadership Group, is an innovative approach to easing access to needed specimens and reducing costly, time consuming and duplicative specimen collection. **IDSA urges the Committee to direct NIAID to explore opportunities to develop virtual biorepositories for other pathogens, such as viruses and fungi.** As mentioned earlier, proposed language is attached for your consideration.

Also noted above, institutional conflict of interest (COI) policies that are significantly more stringent than the NIH COI framework often completely bar key experts and laboratories from collaborating with industry, including diagnostics developers, significantly hampering diagnostics clinical trials. **IDSA urges the Committee to clarify that institutions should adopt COI policies better aligned with the NIH COI framework that allow for appropriate collaboration between industry and researchers.** As mentioned earlier, proposed language is attached for your consideration.)

Ultimately, what needs to be done to ensure that the regulatory environment supports and embraces new clinical trial approaches and designs that reflect the most current understanding of medicine and help to get the best treatments and cures to patients?

As discussed in multiple instances above, the PATH Act is critical for creating a regulatory environment that allows for the conduct of feasible clinical trials for new antibiotics that treat a serious or life-threatening infection and address an unmet medical need. Without such an approach, which has received broad bipartisan support in Congress and among stakeholders, we are deeply concerned that the most urgently needed new antibiotics will not be developed. **As such, IDSA urges the Committee to advance the PATH Act, S. 185, as part of the Innovations effort.**

Also discussed several times above, virtual biorepositories, similar to the existing NIAID-supported bacterial virtual biorepository, would greatly ease clinical trials for new diagnostics by reducing the need for costly, time-consuming and duplicative specimen collection. **IDSA urges the Committee to direct NIAID to explore opportunities to develop virtual biorepositories for other pathogens, such as viruses and fungi.** As mentioned earlier, proposed language is attached for your consideration.

Lastly, institutional conflict of interest policies, also discussed repeatedly above, also pose significant barriers for diagnostics clinical trials when they completely bar academic researchers

from interacting with industry. Such policies are far more stringent than the NIH COI framework. **Clarification from Congress and the NIH that institutional COI policies should align with the NIH framework and allow for appropriate collaboration between academic researchers and industry are crucial for facilitating needed expert support for diagnostics clinical trials.** As mentioned earlier, proposed language is attached for your consideration.

VII. What does the “Gold Standard” look like in the 21st century and beyond?

Should standards be updated to reflect how they are being applied today for both drugs and devices? How certain do we need to be that a drug is safe and effective, and does that differ for different diseases, populations, or circumstances?

Policies regarding antibiotic and infectious diseases diagnostics development must be refined to ensure that these life-saving products are able to reach patients. Ultimately, policymakers must balance the risk of allowing FDA approval for certain urgently needed new antibiotics or diagnostics based upon more limited datasets or different types of data against the even greater risk of a regulatory environment that does not allow for the development and approval of some of the most urgently needed antibiotics and diagnostics.

As discussed above, the PATH Act would allow new antibiotics that treat a serious or life-threatening infection and address an unmet medical need to be approved for a limited population based upon smaller clinical trials. Such an approach is necessary as the targeted infections currently occur in relatively few patients, making it difficult and sometimes impossible to populate traditional, large-scale clinical trials for new drugs to treat these infections. Importantly, the legislation explicitly states that it would not alter the existing FDA evidentiary standard. Drugs approved under this pathway would, therefore, still have to be demonstrated as safe and effective for the limited indicated population. It is also critical to note that the PATH Act contains several provisions designed to guide the appropriate use of new antibiotics approved under the new pathway. Given that PATH drugs would be approved based upon smaller datasets, it is important that they not be used for broader populations of patients who could be successfully treated with traditional antibiotics. **IDSA strongly supports the PATH Act and urges the Committee to advance this critical legislation as part of the Innovations effort.**

With regard to diagnostic tests, in 2014, FDA issued a pair of relevant draft guidance documents entitled, “[Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions](#),” and “[Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval](#).” Together, we believe these draft guidances will help speed patient access to urgently needed new diagnostic tests and we are happy to support these policies. Further, we encourage the Committee to consider ways to build upon this effort. For example, the first discussion draft legislation from the House Energy and Commerce Committee’s 21st Century Cures initiative includes the following two provisions that IDSA supports:

First, IDSA is pleased to support Title I, Subtitle E, a provision to establish priority review for PMA, de novo, and 510(k) breakthrough devices. This provision will speed approval of devices, including diagnostic tests, for which no alternatives exist, as well as tests that offer significant advantages for patients over existing approved or cleared tests. The first above-mentioned draft FDA guidance would similarly expedite access to PMA devices that address an unmet medical need. By extending priority review to lower risk tests that still meet the breakthrough criteria, this provision could speed patient access to a much wider variety of diagnostic tests that could provide much more rapid and reliable results for patients suffering from infectious diseases. Such tests have tremendous potential to improve patient outcomes and shorten hospital stays by facilitating administration of appropriate treatment much earlier in the course of a disease. These diagnostics may also be extremely useful in identifying patients eligible for antimicrobial drug clinical trials.

Second, IDSA supports Title I, Subtitle F, a provision to provide accelerated approval for PMA, de novo and 510(k) breakthrough devices that have an impact on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway is already utilized successfully for drug development and approval, and IDSA supports similar efforts to speed patient access to urgently needed diagnostic tests. For a patient with a serious or life-threatening infection that cannot be identified in a sufficiently rapid manner to substantively impact care and outcomes, FDA must appropriately weigh the risk of approving a new diagnostic test based upon a smaller premarket data set against the risk of not having urgently needed new diagnostics. Importantly, this provision provides for the conduct of post-market studies to verify clinical benefit. Post-market data can allow FDA to continue to clarify uncertainties regarding the benefits and risks of the device without inappropriately slowing or blocking patient access to an urgently needed test.

This provision will be particularly helpful in developing viral load tests for infections such as cytomegalovirus (CMV) that impact transplantation patients. These tests can clearly identify and reliably establish viral load in patients, and can also be used to establish the duration of treatment with optimal efficacy, cost-effectiveness, and patient outcome. However, clinical trials for these tests are extremely difficult because clinical endpoints are rarely reached due to preemptive treatment of high-risk patients. This provision would allow trials to use a surrogate endpoint like quantification of viral load as related to a comparator test, greatly simplifying the trials process. By allowing accelerated approval of these tests, post-market data can be collected to better validate the medical benefits of using these tests as guides for treatment response while not unnecessarily delaying patient access to these important tools.

Are today's regulatory pathways sufficient to ensure a predictable pathway for innovators as they bring forward medical products for review by the agency? Are today's pathways achieving their intended purpose? Are they being fully leveraged on behalf of patients?

Specifically with regard to new antibiotics that would treat a serious or life-threatening infection and address an unmet medical need, IDSA believes that a new regulatory pathway is urgently needed. Such antibiotics often cannot be developed using traditional, large-scale clinical trials

due to the limited number of patients in whom the targeted infections currently occur. As discussed several times above, the bipartisan PATH Act would address this regulatory hurdle by establishing a new pathway that would allow this narrow set of urgently needed antibiotics to be approved for a limited population based upon smaller clinical trials. **IDSA strongly urges the Committee to advance the PATH Act, S. 185, as part of the Innovations effort, and we fear that without such an approach, some of the antibiotics that patients most need will not be developed.**

Regulatory pathways for infectious diseases diagnostic tests could also be significantly improved. As discussed above, the FDA has already taken some important first steps through draft guidance documents issued in 2014. **Two proposed provisions included in the House Energy and Commerce Committee’s discussion draft for 21st Century Cures—priority review and accelerated approval for PMA, de novo, and 510(k) breakthrough devices—would build upon FDA’s efforts and help speed patient access to infectious diseases diagnostic tests that have the ability to significantly improve patient care and public health.**

How should the FDA rely on outside science when developing policy? How should FDA then communicate timely scientific and regulatory policy changes while still allowing for public comment and debate?

Ensuring that antimicrobial susceptibility criteria (commonly referred to as “breakpoints”) are updated in a timely fashion is one instance for which IDSA urges the Committee to provide the FDA with greater authority to rely upon outside science while still retaining final decision-making authority. **IDSA supports Sec. 1062 in the House Energy and Commerce Committee 21st Century Cures discussion draft that would address this issue.**

A breakpoint provides information that helps to predict whether a patient infected with a specific pathogen will have a good clinical response to standard doses of a drug (i.e., whether an antimicrobial drug is expected to successfully treat an infection). Prescribers need accurate and up-to-date breakpoints to guide the selection and dosage of antimicrobial drugs to maximize patients’ chances for positive clinical outcomes. Breakpoints are used in antimicrobial susceptibility testing (AST) devices, results of which serve as the basis for drug selection by clinicians. Inaccurate (including out-of-date) breakpoints can result in health care providers unknowingly selecting ineffective or overly broad spectrum treatments or incorrect dosing, putting patient safety and lives at risk and contributing to the development of antibiotic resistance. Moreover, health care facilities often rely on accurate AST devices to identify patients with dangerous, multi-drug resistant infections for whom certain infection control protocols must be activated to prevent the further spread of the resistant organism. Without updated breakpoints, an AST device may misclassify the susceptibility of infecting pathogens to antibiotic agents, putting patients at risk of misguided and ineffective care, and putting other patients, family members, and others at risk of exposure.

Current statute requires FDA to update breakpoints, but the process for doing so is extremely resource intensive, which leads to significant delays in updating breakpoints. Outside standard setting bodies, such as the Clinical Laboratory Standards Institute (CLSI), convene key expert stakeholders, including FDA representatives, to update breakpoints, but current law requires

FDA to essentially duplicate this work. To help ensure that FDA breakpoints are regularly updated and made available to physicians, AST device manufacturers, and others who may rely upon them, IDSA supports key statutory changes (as included in the House Energy and Commerce Committee 21st Century Cures discussion draft), including:

- Allowing the FDA to review breakpoints updated by external standard setting organizations and, if FDA agrees with a new breakpoint, post the updated breakpoint on its website. If FDA disagrees with a new breakpoint set by an external standard setting organization, the agency should post its reasoning on its website and update the breakpoint itself. Under this new policy, FDA would retain authority over breakpoints, but would be allowed to utilize outside expertise as appropriate—saving significant time and resources.
- Removing breakpoint information from the paper labeling of antimicrobial drugs to minimize potential confusion regarding which information is most up-to-date.
- Allowing the FDA to approve AST devices that incorporate breakpoints that have been set by an external standard setting organization, recognized by FDA, and posted on FDA's website.

VIII. Regulatory Science: The FDA must be prepared to review medical products in the future

How have the resources dedicated to the regulatory science initiatives translated into policy, biomarkers, trial designs, standards, or other outputs that have been used to reduce development and/or review times? How do we assess the success of these programs and partnerships? Have they been successful at achieving their stated purposes and goals?

IDSA members have participated in the Foundation for the NIH (FNIH) Biomarkers Consortium's efforts to develop new endpoints for trials of antibacterial drugs — an effort that was initiated at FDA's request. Although much work remains to be done, we note that important progress has been made recently.

In 2010, the Biomarkers Consortium began to address the lack of readily quantifiable, reproducible, externally verifiable and feasible endpoints for modern clinical trials in community-acquired bacterial pneumonia and acute skin infections. The FNIH convened scientists from across academia, government, and industry to develop an historic consensus on new trial endpoints. These new endpoints have already played a role in the approval of one new antibacterial drug (ceftaroline fosamil). The FNIH project team is currently developing and validating additional specific outcome measures to support future clinical trials in these infections. In addition, the FDA has incorporated the Biomarkers Consortium's recommendations into regulatory guidances.

FDA again approached the Biomarkers Consortium for assistance with evaluating new endpoints for hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP). These difficult-to-treat, increasingly drug-resistant infections cause high morbidity and mortality. Progress on clinical trial endpoints to allow the development of novel antibacterial

treatments is essential. The FNIH project team has already submitted to the FDA a set of interim considerations for design and conduct of clinical trials for these indications; a number of the FNIH conclusions now appear in a recently issued FDA draft guidance.

IDSA members have also participated in the Clinical Trials Transformation Initiative (CTTI), which was established by Duke University and the FDA as a public-private partnership in 2007 and now comprises over 60 member organizations engaging patients and experts to facilitate discussion of current practices and challenges in the design and conduct of antibiotic trials and to develop novel approaches to overcome these challenges. CTTI's work focuses in three areas:

1. **HABP/VABP:** CTTI is developing recommendations on alternate study design elements to overcome barriers to research. To accelerate the study process, CTTI is generating a prototype study protocol that could be less burdensome to investigators and patients and reduce inefficiencies and costs of drug development. CTTI continues to focus on streamlining protocol elements, as well as seeking practical, more efficient approaches for data collection and operational processes.
2. **Unmet Need:** CTTI is identifying and assessing new approaches for weighing the benefits, risks, and uncertainties of potential new antibacterial drugs in unmet need situations. Patients' and caregivers' tolerance for risk and willingness to be treated with drugs approved through non-traditional trials will be explored.
3. **Pediatric Populations:** CTTI will identify best practices and recommendations on how industry might comply with the Pediatric Research Equity Act (PREA) recommendations for anti-infective drugs. CTTI will facilitate development of new antibacterial drugs and advance the knowledge for conducting successful trials in pediatric populations.

Taken together, the evidence and consensus building through the FNIH Biomarkers Consortium, CTTI and other public private partnerships will contribute to simplifying and speeding up the clinical study process for antibiotic development in areas of critical, unmet medical need. **The Committee should continue encouraging FDA to remain engaged with these entities and to rapidly adopt their findings and recommendations into improved clinical trial guidances.**

IX. Rising Global Competition to U.S. Medical Product Development

How can Congress and the FDA work to align public policy and regulation to support biomedical research as a vibrant and healthy component of the U.S. economy? What can be learned and leveraged from successful international programs and initiatives to improve our domestic discovery and development programs?

All of the recommendations mentioned above will provide significant and much needed support for infectious diseases research. With regard to what can be learned from successful international programs, we again highlight the European Union's Innovative Medicines Initiative (IMI) and specifically its New Drugs for Bad Bugs (ND4BB) project and its Rapid Point-of-care test Platforms for Infectious Diseases (RAPP-ID) project. While the U.S. does have multiple public private partnerships, we do not have one that fosters the comprehensive cooperation that

the IMI has made possible overseas. For the development of new antibiotics and diagnostics, public private partnerships in the U.S. (such as those supported through BARDA) have been extremely valuable, yet limited in that they typically involve a federal partner working with an individual company on an individual project. The IMI model instead facilitates collaboration that includes sharing of data, ideas, and resources among multiple companies, academic researchers, federal experts and other stakeholders. **IDSA strongly encourages the Committee to establish a forum in the U.S. similar to the EU's Innovative Medicine Initiative that facilitates collaboration among multiple stakeholders.**

What are the opportunities to streamline and harmonize regulation and review of medical products to ensure that the U.S. regulatory system remains competitive and attractive to drug and device innovators in a global economy?

In November, 2013, the European Medicines Agency (EMA) published an [addendum](#) to its guidance on the evaluation of medical products indicated for the treatment of bacterial infections. The addendum focused specifically on clinical development of antibiotics for which limited clinical data may be accepted because they address unmet clinical needs such as the potential to treat infections due to multi-drug resistant organisms for which only few or no remaining therapeutic options are available. The EMA's approach is well aligned with the limited population antibiotic pathway that the bipartisan PATH Act, discussed numerous times above, would establish. It is important that the U.S. adopt this approach to ensure that some of the most urgently needed antibiotics are not only developed and marketed in Europe, but also made available for patients in the U.S. **IDSA strongly urges the HELP Committee to advance the PATH Act as part of the Innovations effort.**

Once again, IDSA greatly appreciates the Committee's focus on biomedical innovation and particularly this opportunity to provide comments. We look forward to working with you to develop and advance legislation to help facilitate the research and development for urgently needed new antimicrobial drugs, diagnostics and vaccines to benefit patients and public health. As the Committee continues to pursue the Innovations effort, **we encourage you to hold a hearing or roundtable to discuss some of the unique issues facing products to prevent, diagnose and treat infectious diseases, particularly new antibiotics to treat serious or life-threatening infections.** IDSA would be delighted to provide expertise on any of the issues raised in this letter. If you have any questions, please feel free to contact Amanda Jezek, IDSA's Vice President for Public Policy and Government Relations, at ajezek@idsociety.org or 703-740-4790.

Sincerely,



Stephen B. Calderwood, MD, FIDSA
IDSA President

Enclosures: IDSA Summary of Comments to Senate Innovations White Paper

Draft Virtual Biorepository Legislative Language
Draft Conflict of Interest Legislative Language

Summary of Infectious Diseases Society of America (IDSA) Comments on
Innovation for Healthier Americans:
***Identifying Opportunities for Meaningful Reform to Our
Nation's Medical Product Discovery and Development***

Although many of the comments from the Infectious Diseases Society of America (IDSA) address several of the questions posed in the **Innovation for Healthier Americans**, below is a compilation of the various recommendations organized according to the titles of the report. As mentioned in our comments, we are sharing proposed language on two provisions (virtual biorepository and conflict of interest) for your consideration. IDSA strongly urges the HELP Committee to advance the **Promise for Antibiotics and Therapeutics for Health (PATH) Act, S. 185** as part of the Innovation initiative. Also, we have highlighted specific provisions of the House Energy and Commerce Committee's 21st Century Cures January 26, 2015 discussion draft which IDSA supports and believes they address questions raised by the HELP Committee.

IV. It Takes Too Long and Costs Too Much to Develop Medical Products for American Patients

- Robust funding for the National Institute of Allergy and Infectious Diseases (NIAID) is needed to support activities of the Antibacterial Resistance Leadership Group (ARLG)
- Increased funding for the Biomedical Advanced Research and Development Authority (BARDA) is necessary to improve access to cutting edge medical products.
- Coverage for all Advisory Committee on Immunization Practices (ACIP) recommended vaccines should be required through both Medicare Part B and D to ensure that no senior falls through the cracks.
- Conduct oversight for the Protecting Access to Medicare Act of 2014 (PAMA) expert advisory panel, which will provide input on the development, validation, performance, and application of clinical laboratory tests, to ensure infectious diseases experts are included.
- Conduct appropriate oversight of the New Technology Add-On Payment (NTAP) program to help ensure that new antibiotics are appropriately evaluated.
- Consider legislation that would specifically improve reimbursement for new antibiotics, such as Sec. 1064 of the House Energy and Commerce Committee's 21st Century Cures discussion draft. In order to appropriately target limited federal resources, IDSA recommends that such legislation be applied to new antimicrobial drugs that treat a serious or life-threatening infection and address an unmet medical need.
- Direct NIAID to examine opportunities to support the development of **virtual biorepositories** for viruses, fungi and other pathogens, utilizing samples already being collected under existing NIAID-funded research, similar to the existing bacteria virtual biorepository (proposed language attached for your consideration) and provide incentives and support for institutions to save de-identified specimens and to participate in virtual biorepository catalogues when possible.

- **Develop a public private partnership complementary to the European Union’s Innovative Medicine’s Initiative (IMI)** to facilitate collaboration among stakeholders including academic groups, informatics groups, and large and small companies.

V. **From Bench to Bedside: The Role of Basic Research in New Medical Products**

- Ensure strong, stable NIH funding
- Clarify that institutions receiving federal funding should implement **conflict of interest (COI)** policies that appropriately enable transparent industry/institutional research collaborations. (proposed language is attached for your consideration)
- Direct the Agency for Healthcare Research and Quality (AHRQ) Center for Evidence and Practice Improvement (CEPI) to **conduct or support research to demonstrate the impact of new infectious diseases diagnostics on patient care and outcomes, and to disseminate the results** of that research to physicians to encourage them to appropriately utilize new diagnostics.

VI. **Opportunities to Improve Clinical Trials**

- Advance the **Promise for Antibiotics and Therapeutics for Health (PATH) Act**, S. 185
- Direct NIAID to examine opportunities to support the development of **virtual biorepositories** for viruses, fungi and other pathogens, utilizing samples already being collected under existing NIAID-funded research, similar to the existing bacteria virtual biorepository (proposed language attached for your consideration) and encourage the Committee to provide incentives and support for institutions to save de-identified specimens and to participate in virtual biorepository catalogues when possible.
- Clarify that institutions receiving federal funding should implement **conflict of interest (COI)** policies that appropriately enable transparent industry/institutional research collaborations. (proposed language is attached for your consideration)
- Robust funding for the National Institute of Allergy and Infectious Diseases (NIAID) is needed to support activities of the Antibacterial Resistance Leadership Group (ARLG)

VII. **What does the “Gold Standard” look like in the 21st century and beyond?**

- Advance the **Promise for Antibiotics and Therapeutics for Health (PATH) Act**, S. 185
- Establish priority review for PMA, de novo, and 510(k) breakthrough devices (similar to Title I, Subtitle E of the House Energy and Commerce Committee discussion draft)
- Provide accelerated approval for PMA, de novo and 510(k) breakthrough devices that have an impact on a surrogate endpoint that is reasonably likely to predict clinical benefit, or a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit (similar to Title I, Subtitle F of the House Energy and Commerce Committee discussion draft)
- **Ensure that antimicrobial susceptibility criteria (“breakpoints”) are updated** in a timely fashion by providing FDA with greater authority to rely upon outside science while still retaining final

decision-making authority (e.g., Sec. 1062, House Energy and Commerce Committee discussion draft)

VIII. Regulatory Science: The FDA must be prepared to review medical products in the future

- Encourage FDA to remain engaged with the Foundation for the NIH (FNIH) Biomarkers Consortium, Clinical Trials Transformation Initiative (CTTI) and other public private partnerships that will contribute to simplifying and speeding up the clinical study process for antibiotic development in areas of critical, unmet medical need, and to rapidly adopt their findings and recommendations into improved clinical trial guidances.

IX. Rising Global Competition to U.S. Medical Product Development

- **Develop a public private partnership complementary to the European Union's Innovative Medicine's Initiative (IMI)** to facilitate collaboration among stakeholders including academic groups, informatics groups, and large and small companies.
- Advance the **Promise for Antibiotics and Therapeutics for Health (PATH) Act**, S. 185

1 **SEC. XX. VIRTUAL REPOSITORY OF INFECTIOUS DISEASES**
2 **SPECIMENS.**

3 (a) AMENDMENT.—Part B of title IV of the Public Health Service Act (42
4 U.S.C. 284 et seq.) is amended by adding at the end the following:

5 **“SEC. XXX. VIRTUAL INFECTIOUS DISEASES SPECIMEN**
6 **BIOREPOSITORY**

7 “(a) IN GENERAL.—The Secretary, acting through the Director, in
8 consultation with the Director of the Centers for Disease Control and Prevention,
9 the Assistant Secretary for Preparedness and Response, and the Commissioner of
10 the Food and Drug Administration, shall examine the feasibility, either directly or
11 by contract, of a virtual biorepository of human biological specimens or isolates to
12 assist with lowering the cost of clinical trials of, and otherwise assisting with the
13 research and development for, qualified diagnostic tests or other activities intended
14 to advance the treatment, detection, identification, prevention or control of
15 infectious diseases;

16 “(c) KEY ELEMENTS. – In examining the feasibility of a virtual
17 biorepository under (a), the Secretary shall examine the feasibility of --

18 “(1) Self-Sustaining Capacity. —a self-sustaining virtual
19 biorepository in which the Secretary establishes a program under which non-
20 governmental entities could pay a fee for access to each human biological
21 specimen or isolate, including costs related to the overall maintenance and
22 operation of the virtual biorepository;

23 “(2) Incentives for participation. – establishing various incentives for
24 clinical and research laboratories to freeze human biological specimens
25 containing or isolates of novel or unusual organisms for further use and
26 submit such specimens or isolates including biorepository data to the virtual
27 biorepository.

1 “(3) Expanding current efforts. – expanding participation in, and
2 access to, the current virtual bacterial biorepository supported by the
3 Antibacterial Resistance Leadership Group.

4 (4) Template for virtual biorepository.—utilizing the existing virtual
5 bacterial biorepository’s structure and practices as a template for any
6 additional biorepository which may include additional types of pathogens,
7 such as viruses and fungi.

8 “(d) REPORT. Not later than one year after the date of the enactment of this
9 section, the Secretary shall submit to the appropriate committees of Congress a
10 report regarding the virtual biorepository. Such report shall contain the potential
11 establishment of such biorepository, the feasibility of making such biorepository
12 whether such biorepository will be self-sustaining, any potential incentives for
13 participation, the potential for expanding the current virtual bacterial biorepository,
14 and whether the Secretary intends to utilize the current template of a virtual
15 biorepository for further expansion.

16 “(e) DEFINITIONS.—In this section:

17 “(1) BIOREPOSITORY.—The term ‘biorepository’ means a repository
18 of human biological specimens containing infectious pathogens (including
19 bacterial, viral, fungi, and other pathogens), or isolates, previously collected
20 for medical or research purposes (including other NIH sponsored research)
21 that includes biorepository data.

22 “(2) BIOREPOSITORY DATA—The term ‘biorepository data’—

23 “(A) means data associated with a human biological specimen
24 stored in an institution participating in a virtual biorepository
25 collected for medical or research purposes; and

26 “(B) includes patient health information and demographic data
27 associated with a specimen.

1 “(3) DIAGNOSTIC TEST.—The term ‘diagnostic test’ is a device as
2 defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 321).

4 “(3) HUMAN BIOLOGICAL SPECIMEN.—The term ‘human biological
5 specimen’ means any human body fluid, tissue, blood, or cell; and any
6 material derived from any human body fluid, tissue, blood, or cell.

7 “(4) ISOLATE. – The term ‘isolate’ means an isolated pathogen from
8 a human biological specimen.

9 “(5) QUALIFIED DIAGNOSTIC TEST.—The term ‘qualified diagnostic
10 test’ means a diagnostic test that is approved after the date of enactment of
11 this Act under section 510 or 515 of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 360; 21 U.S.C. 360e), including a point-of-care diagnostic
13 test, for treating, detecting, preventing, or identifying an infectious pathogen.

14 “(6) VIRTUAL . – The term ‘virtual ’ means a web-based system that
15 provides researchers with the capacity to search for and access human
16 biological specimens or isolates within a biorepository so that human
17 biological specimens or isolates can be stored at different locations.

18 “(7) VIRTUAL BIOREPOSITORY. – The term ‘virtual
19 biorepository’ means a biorepository that is virtual.
20
21

1 **SEC. XX. ADDRESSING BURDENSOME CONFLICTS OF INTEREST**
2 **FOR NIH-FUNDED ENTITIES**

3 (a) FINDINGS. -- Congress makes the following findings:

4 (1) Federal conflict of interest policies are not intended to prohibit
5 collaboration between industry and academic researchers.

6 (2) The National Institutes of Health (NIH) issued revised regulations
7 related to Conflict of Interest in 2011

8 (3) NIH's revised regulation promotes objectivity in research by
9 establishing standards that provide a reasonable expectation that the
10 design, conduct, and reporting of research performed under NIH
11 grants or cooperative agreements will be free from bias resulting
12 from Investigator financial conflicts of interest. This regulation is
13 commonly referred to as the Financial Conflict of Interest (FCOI)
14 regulation.

15 (a) AMENDMENT.—Part B of title IV of the Public Health Service Act (42
16 U.S.C. 284 et seq.) is amended by adding at the end the following:

17 **“SEC. XXX. APPROPRIATE CONFLICT OF INTEREST**
18 **REQUIREMENTS**

19 “(a) IN GENERAL.—The Secretary, acting through the Director of NIH, shall
20 ensure that persons applying for or receiving funding from this Part from a grant,
21 cooperative agreement, or contract establish appropriate conflict of interest
22 requirements that are not more burdensome or restrictive than the conflict of
23 interest framework outlined by NIH under 42 CFR Part 50 and 45 CFR Part 94. In
24 ensuring the appropriate application of conflict of interest requirements, the
25 Director of NIH shall also promote consistency in interpretation and
26 implementation of such policies. s

1 (b) EFFECTIVE DATE. – The effective date of this provision shall be two
2 years after the date of enactment of this act.

3