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**Energy and Commerce Committee, Health Subcommittee  
U.S. House of Representatives  
*21st Century Cures: Examining Ways to Combat Antibiotic Resistance  
and Foster New Drug Development***

**September 19, 2014**

Thank you for inviting me to testify on behalf of the Infectious Diseases Society of America (IDSA) on the public health crisis of antibiotic resistance and the urgent need for new antibiotics, diagnostics and vaccines. IDSA is grateful for this Subcommittee's leadership in addressing these critical issues and advancing policies to combat resistance and save lives.

**Antibiotic Resistance: A Public Health Crisis**

Antibiotics are generally accepted as the greatest development in medical therapeutics of the 20th century and are now credited with a 26 year increase in average longevity. For example, before the discovery and development of antibiotics, 100% of patients who contracted heart valve infections died from that infection. Now the mortality rate for heart valve infections is around 25%. Similarly, in the pre-antibiotic era, over 80% of patients with brain infections died. Now, over 80% of patients with brain infections survive, thanks to antibiotics. Unfortunately, this tremendous progress is seriously threatened by the rapid rise of antibiotic-resistant bacteria coupled with a persistent market failure to develop new antibiotics. This public health crisis has been well documented by the Centers for Disease Control and Prevention's (CDC's) [Antibiotic Resistance Threats 2013](#) report, the [World Health Organization](#) and multiple other government entities and non-government experts, including IDSA with our [2004 Bad Bugs, No Drugs report](#) and our [2011 Combating Antimicrobial Resistance: Policy Recommendations to Save Lives](#)

[report](#). We are on the very real, very frightening precipice of a post-antibiotic era with mortality rates for infections increasing.

IDSA is advocating for new antibiotics and diagnostics to improve and save the lives of the many patients who are suffering from serious or life-threatening infections. At my own institution in Texas, my colleagues and I are seeing more and more patients of all ages with serious or life-threatening infections that are resistant to all or nearly all available antibiotics. I would like to share a few of these patient stories with you.

I saw a young adult patient with severe lupus (a chronic, non-infectious, auto-immune disease in which the patient's immune system attacks his or her own body). This young woman developed a bile duct and bloodstream infection caused by the bacterium, *Pseudomonas aeruginosa*. She was in significant pain. Over several months, the infection persisted despite all the antibiotics we tried, and the *Pseudomonas* became increasingly resistant to every available antibiotic, including Colistin — a toxic drug of last resort because it damages the kidneys. Despite even surgical interventions, her infection and marked pain persisted. All we could do was send her to hospice for palliative comfort care while she waited for the infection to claim her life.

A colleague of mine had another patient in his sixties who had been healthy and active.

Following joint replacement surgery, he developed a *Pseudomonas* infection in the prosthetic joint. Despite removal of the prosthetic joint and multiple antibiotics, the infection could not be controlled and he had to have an above-the-knee amputation. For one facing possible future joint replacements, this is a truly frightening complication.

This summer I cared for two patients with diabetes and urinary tract infections (UTI) caused by a highly resistant strain of *E. coli*. Both patients had to be admitted to the hospital for intravenous therapy because their infections were resistant to all oral antibiotics, and they were not candidates for home intravenous (IV) therapy (and our system is not set up for daily outpatient IV injections). There is now **no** reliable oral antibiotic for complicated UTIs. Having to hospitalize patients or, at the least, insert a catheter for self administration of antibiotics at home (which has its own problems), for such a common infection that could previously be treated effectively with oral antibiotics, markedly increases our health care costs (as well as increases inconvenience, potential complications and decreases productivity). Probably every woman by the age of 60 has had at least one UTI, illustrating the enormity of the problem.

### **Urgent Need for New Life-Saving Antibiotics**

IDSA is extremely appreciative of this Committee's leadership, and especially Congressmen Phil Gingrey and Gene Green, in enacting the Generating Antibiotic Incentives Now (GAIN) Act in 2012. This legislation not only provides an additional 5 years of exclusivity for new antibiotics that treat serious or life-threatening infections, but it also signals to the health care community and the patients who depend on us, that Congress is committed to addressing antibiotic resistance and providing physicians with the tools we need to effectively treat our patients. Today's hearing demonstrates this Subcommittee's ongoing dedication to finding and advancing policy solutions, and IDSA is delighted to continue working with you.

Despite the success of the GAIN Act, companies still face significant economic, regulatory and scientific barriers to antibiotic development—particularly when it comes to developing new drugs to treat some of the most deadly and highly resistant infections, such as those caused by Gram-negative bacteria (one of two major classes of bacteria, with the Gram-positive class represented by “MRSA”). One key example is carbapenem resistant Enterbacteriaceae or CRE—dubbed the “nightmare bacteria” by CDC last year. CRE germs kill up to half of patients who get bloodstream infections from them. About 18% of U.S. long-term acute care hospitals had at least one patient with a serious CRE infection during the first half of 2012, and this deadly pathogen is continuing to spread. Even more frightening—we have no safe and effective antibiotics to treat CRE. [An April 2013 analysis of the antibiotic development pipeline conducted by IDSA](#) found only a few new drugs in development for the treatment of infections caused by multidrug-resistant Gram-negative bacteria. Given the high predicted failure rate in clinical trials, it is quite possible that none of these will make it across the finish line to Food and Drug Administration (FDA) approval. Moreover, none of them will work against the pan-resistant pathogens (or those resistant to all current antibiotics).

Why are pharmaceutical companies facing such difficulty in developing new antibiotics to treat CRE and other serious or life-threatening infections caused by multi-drug resistant disease-causing bacteria? As the Subcommittee may recall from its deliberations on the GAIN Act, antibiotics research and development (R&D) faces very significant economic hurdles.

Antibiotics are typically priced low, used for a short duration, and held in reserve by physicians to protect against the development of resistance. The GAIN Act took an important first step to

begin providing an economic incentive for companies to invest in new antibiotic development. But Congress must still do more.

### **ADAPT Act: Removing Regulatory Barriers to Antibiotic R&D**

Companies who now wish to develop some of the most urgently needed new antibiotics are facing serious regulatory barriers. Some of the most dangerous pathogens are to date occurring in relatively small numbers of patients, making it difficult or 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. However, 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 traditional clinical trials. Compounding the problem is the lack of rapid diagnostic tests to quickly identify patients infected with certain pathogens who may be eligible for antibiotic or antifungal clinical trials early enough to improve their outcomes and to avoid enrolling patients only to find out 24-48 hours later that they are not eligible, which adds markedly to the overall cost of the trial without gaining useful efficacy information.

IDSAs thanks Representatives Gingrey and Green for continuing to lead the effort to incentivize antibiotic development by introducing the Antibiotic Development to Advance Patient Treatment (ADAPT) Act, H.R. 3742, and we urge the Subcommittee to markup this important bill.

ADAPT would help address some of these serious regulatory hurdles by creating a new FDA approval pathway in which companies could study in smaller clinical trials new antibacterial or antifungal drugs to treat serious or life-threatening infections for which there is an unmet medical

need. ADAPT drugs would receive approval just for the limited population in most need of the therapy, as opposed to all patients. Smaller clinical trials can also be less costly to companies, which is an important consideration given the economic hurdles still facing antibiotic R&D.

The ADAPT Act would speed patient access to desperately needed, life-saving new drugs for infections for which there are very limited or no therapeutic options, and it includes important provisions to help guide the appropriate use of these drugs. For example, ADAPT requires that the labeling of drugs approved under the limited population pathway explicitly state: “This drug has been approved for a limited and specific population.” In addition, FDA would have the authority to pre-review any promotional materials for ADAPT drugs to ensure these drugs are not marketed inappropriately. This policy is identical to what FDA does under the successful accelerated approval pathway. Lastly, the use of ADAPT drugs would be monitored under CDC’s existing National Healthcare Safety Network (NHSN). IDSA believes that the bill could be further strengthened to ensure that the labeling of drugs approved under this new pathway clearly and prominently illustrate that these drugs are indicated for a limited population. It is important to make it as simple as possible for the health care community to easily recognize that these drugs have been approved in a different manner than traditional antibiotics and should be used appropriately.

The ADAPT Act provides a critical incentive to companies to develop the most urgently needed new antibiotics. In addition to simply making these clinical trials feasible by allowing them to be smaller, ADAPT would reduce some of the significant expense and administrative and regulatory burdens associated with traditional, large scale clinical trials that are not practical or

even possible with these infections. In addition, to help ensure to as great an extent as possible that the drugs are safe and effective for the limited indicated population, the FDA could also consider different types of data (such as pre-clinical and volunteer pharmacologic or pathophysiologic data, data from phase 2 clinical studies, and other confirmatory evidence) when determining a new drug's approval under the ADAPT Act.

The ADAPT Act also contains important provisions designed to ensure that susceptibility test interpretive criteria (commonly referred to as "breakpoints") for antimicrobial drugs are regularly updated in a timely fashion, and that updated breakpoints are made publicly available via FDA's website. 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. Given the ongoing development of drug resistance, it is critical that breakpoints be regularly updated to provide physicians with accurate information to guide the optimal use of drugs in patients.

We are very grateful to all of the Subcommittee members who have already cosponsored the ADAPT Act, and hope that after today's hearing, many more of you will want to lend your support. [Numerous medical societies and public health organizations](#) share IDSA's view of this important legislation. As the Committee heard during its recent May 20<sup>th</sup> hearing, "*21st Century Cures: The President's Council of Advisors on Science and Technology (PCAST) Report on Drug Innovation*," PCAST endorsed a limited population approach to antibiotic development in its 2012 report. IDSA believes that without an approach to antibiotic development like the one the ADAPT Act would establish, many of the drugs our patients need to stay alive simply cannot

and will not be developed. On behalf of those patients, we urge you to swiftly advance the ADAPT Act.

### **Additional Economic Incentives for Antibiotic R&D**

While the ADAPT Act would create a feasible pathway for the development of the most urgently needed new antibiotics, expert stakeholders agree that additional economic incentives are required (including tax credits, additional funding for critical agencies, and new public-private partnerships). Due to significant scientific challenges and regulatory hurdles, development of new antibiotics—particularly to treat some of the most highly-resistant and most deadly infections—can be extremely expensive. Net present value (NPV) describes the relationship between a drug's R&D costs versus its potential return on investment. Companies use NPV to decide whether to move forward with one drug versus a competing drug the company is able to available to invest in at a given time. Due to high R&D costs, insufficient federal support for antibiotic R&D, and inadequate opportunity to earn a satisfactory return on investment, antibiotics have a very low NPV. Some research even indicates some antibiotics' NPV is a negative number, meaning the company would actually lose money by bringing the drug to market.

### *Federal Agencies Supporting Antibiotic R&D*

IDSAs also recognizes that multiple federal agencies provide critical investments in antibiotic R&D. We encourage the Subcommittee to consider how Congress can best support these efforts. The National Institutes of Health (NIH) National Institute for Allergy and Infectious Diseases (NIAID) recently established 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 focusing on antibacterial drug and diagnostic development, optimal usage strategies, infection control and activities to limit the development of resistance.

In 2010, The Biomedical Advanced Research and Development Authority (BARDA) established a Broad Spectrum Antimicrobials (BSA) Program to focus on developing novel antibiotics to address biological threats as well as the public health threat of antibiotic resistance. In four years, the BARDA program has grown from supporting one industry partnership with an antibiotic candidate in Phase 2 development to six partnerships with three industry partners in Phase 3 clinical development. Since 2010, BARDA has awarded over \$550 million to companies for antibiotic development.

IDSAs also encourage the Committee to be mindful of CDC's role in research and innovation. For example, CDC's proposed [Detect and Protect Against Antibiotic Resistance initiative](#) – which has [broad support](#) – includes the establishment of a bacterial isolate library that could be very useful to researchers and companies for the development of new antibiotics and diagnostics.

While not under this Subcommittee's jurisdiction, the Defense Threat Reduction Agency (DTRA), and the Defense Advanced Research Projects Agency (DARPA) have also been important sources of funding for antibiotic research, particularly focusing on threats to our warfighters.

### *Public Private Partnerships*

While individual federal agencies are effectively partnering with individual pharmaceutical companies to pursue antibiotic R&D, the U.S. lacks a large-scale public private partnership (PPP) to convene the diverse stakeholders required to tackle the challenges facing antibiotic R&D. The European Union has launched an impressive PPP, New Drugs for Bad Bugs (ND4BB), under its Innovative Medicines Initiative (IMI). 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 in order to meet the challenges of antibiotic resistance quickly and efficiently.

At a late July joint NIH/FDA meeting on antibiotic development, NIH Director Dr. Francis Collins announced that the U.S. would launch a new public private partnership on antibiotic development and would pursue the creation of a master clinical trials protocol for antibiotics. We appreciate that Congressman Gene Green asked Dr. Collins for additional information on this effort during a recent 21<sup>st</sup> Century Cures roundtable. IDSA is encouraged by the NIH announcement and looks forward to additional information from NIH and other federal partners about how we can best support these activities. We urge the Subcommittee to express its support for these initiatives as well.

### *Tax Credits*

A variety of economic experts agree that a combination of “push” and “pull” incentives are needed to effectively stimulate antibiotic R&D. The GAIN Act provides a valuable “pull”

incentive (additional exclusivity). Improving reimbursement for the most urgently needed new antibiotics would be another important pull incentive. We urge you to work with other Congressional committees to provide targeted tax credits for antibiotic R&D. Tax credits would provide an extremely valuable “push” incentive and would be a very important complement to other efforts undertaken by this Subcommittee. IDSA has developed a proposal to provide a credit of 50 percent of the qualified clinical testing expenses (which we would define as expenses incurred in phase 2 and 3 clinical trials) for new antibiotics and antifungal drugs to treat serious or life-threatening infections—the very same drugs eligible for the additional 5 years of exclusivity under the GAIN Act (life-saving new drugs that this Subcommittee deemed worthy of federal investment). Economic modeling has indicated that financial support during expensive clinical trials, as provided through tax credits, would be a powerful incentive to complement enhanced exclusivity and reimbursement. In fact, Ernst & Young analysis estimated that our tax credit proposal would result in an additional 5-7 new antibiotics or antifungal drugs to treat serious or life-threatening infections in the pipeline every year.

### *Reimbursement Reform*

Reimbursement mechanisms can be used to help stimulate antibiotic R&D, such as through the [Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms \(DISARM\) Act, H.R. 4187](#). This bill would provide Medicare add-on payments for antibiotics used in inpatient settings to treat infections associated with high rates of mortality. Strong communication between the Centers for Medicare and Medicaid Services (CMS) and FDA is critical for the success of such efforts, to help ensure that criteria to determine a drug’s coverage and payment are applied in a scientifically and medically appropriate and consistent manner that provides

companies with the certainty and predictability they need in order to develop life-saving new antibiotics. It is also very important to monitor the use of antibiotics that receive this increased reimbursement.

### **Combating Antibiotic Resistance**

While incentivizing the development of new antibiotics is critical, it is equally important that the Committee take a leadership role in developing and implementing a national strategy to address antibiotic resistance. Key elements of a successful strategy should include well coordinated federal leadership; sustained and meaningful involvement of non-government stakeholders; antibiotic stewardship; enhanced surveillance and data collection on antibiotic use and resistance patterns; and research on novel strategies, best practices and evaluation of methods to prevent, control, and eradicate antimicrobial resistant organisms.

#### *Federal Leadership and Coordination*

The U.S. Interagency Task Force on Antimicrobial Resistance (ITFAR) is charged with coordinating federal efforts in this area. However, the ITFAR lacks the high-level, centralized leadership it needs to ensure measurable progress and accountability. We urge you to designate a Director at a high level of government --either in the White House or under the Secretary of Health and Human Services (HHS)-- to lead the ITFAR and coordinate the Federal response. This enhanced leadership would help facilitate better coordination, including a stronger ongoing dialogue with nongovernment experts. The problem of antibiotic resistance is so significant that government must work collaboratively with a broad array of key stakeholders. IDSA continues to advocate for the creation of a formal advisory board of non-government experts to meet with

the ITFAR on a regular basis. In addition, earlier this month we officially launched the new [Stakeholder Forum on Antimicrobial Resistance \(S-FAR\)](#), which includes 80 member organizations representing health care providers, patients, hospitals, public health, advocates and industry. S-FAR will hold its inaugural meeting with key federal leaders in October 2014.

#### *Antimicrobial Stewardship Programs in Every Health care Facility*

Antimicrobial stewardship programs must also play a central role in our efforts to combat resistance across the continuum of care. Over the last several decades, there has been a dramatic increase in antibiotic use in hospitals and outpatient settings. Antibiotics may be prescribed needlessly and continued when no longer necessary. Such overuse and misuse is driving the development of antibiotic resistance. Antibiotic stewardship is a critical tool to protect antibiotics from misuse and overuse. Antibiotic stewardship can better patient care, improve outcomes, and lower the healthcare costs associated with antibiotic overuse as well as costs associated with infections and antibiotic resistance. IDSA has proposed that the CMS require health care facilities to implement antimicrobial stewardship programs as a condition of participation in Medicare, and we hope that the Committee will join us in encouraging CMS to adopt this policy.

#### *Strengthening Surveillance and Data Collection*

To thoroughly monitor the impact of stewardship programs and other interventions, we need real time, publicly available data on antibiotic usage and antibiotic resistance. Our current surveillance and data collection in these areas are sporadic and contain many gaps. Improved surveillance and data collection are critical for determining the prevalence of resistant infections,

determining antibiotic and diagnostic development priorities, and defining metrics and allowing benchmarking.

The CDC's new [Detect and Protect Against Antibiotic Resistance initiative](#) (as proposed in the President's Budget Request for Fiscal Year 2015 at \$30 million) would improve surveillance. One piece of the initiative would create a detection network of five regional labs to speed up identification of the most concerning threats and increase susceptibility testing for high priority bacteria.

The President's Budget also requested a \$14 million increase for NHSN. This additional funding would support increased uptake of NHSN's antibiotic resistance and antibiotic use modules — two tools that allow for centralized reporting of antibiotic use and resistance (AUR) data. Currently, 12,000 facilities report some type of data through NHSN, but only a small fraction of those facilities are reporting AUR data. CDC recently launched a new AUR reporting module and is onboarding new facilities, but more funding is needed to expand reporting. Once more facilities across the country are capable of reporting these data, CDC can create a prescribing index to help benchmark antibiotic use across health care facilities, allowing facilities to compare their data with similar facilities. It will also help state, local and federal public health entities to identify antibiotic use and resistance hot spots within a city or a region. Finally, health care providers, researchers and the public will be able to view and study the data via a web-based portal. It is critical that antibiotic resistance and use data, and gaps in those data, be made public on a regular basis. IDSA greatly appreciated the [2013 CDC report](#) on this issue and recommends that these data be reported on a regular basis. The proposed funding increase will improve our

understanding of antibiotic resistance threats and bring the clear public health benefits of such data to the public faster.

### **Investing in Diagnostics R&D and Clinical Integration**

New diagnostic tools are also crucial for combating resistance. Emerging diagnostic technologies help guide appropriate use of antibiotics and decrease antibiotic misuse and overuse by lessening the need for clinicians to treat patients empirically and permitting use of narrow spectrum agents to minimize collateral damage to normally present host microorganisms. However, there are significant challenges to the development, regulatory approval and clinical integration of new diagnostic tests.

IDSA's 2013 report, [Better Tests, Better Care: Improved Diagnostics for Infectious Diseases](#) makes policy recommendations to help spur the development of new and more rapid diagnostic tests and encourage their use in patient care and public health.

IDSA urges you to work with your colleagues on the Appropriations and Ways & Means Committees to provide robust funding for diagnostics research through NIAID, BARDA and tax credits. The NIAID Small Business Innovation Research (SBIR) program is an important source of funding for diagnostics research, and additional resources would expand this program's impact. IDSA also urges the Committee to support NIAID, where appropriate, in its efforts to address the most urgent diagnostics needs. For example, NIAID should work to ensure that the peer review process for diagnostics grant submissions includes study sections with appropriate expertise to evaluate feasibility and clinical applicability, as well as scientific merit. IDSA

applauds NIAID's recently announced \$12 million funding initiative geared toward research on diagnostics to quickly detect bacteria responsible for antibacterial resistant infections in hospital settings, and we hope to see continued focus in on this priority area.

It is also critical to reduce regulatory barriers to diagnostics R&D, specifically by working with the FDA Center for Devices and Radiological Health (CDRH) to facilitate the development of point of care tests. Currently, some novel diagnostic tests for certain pathogens must be approved through the premarket approval (PMA) pathway, which can be cost prohibitive and time-consuming, especially for smaller companies. In addition, study designs that call for comparing superior new diagnostics to outdated reference tests can add considerable time and cost to trials. The FDA has taken several promising steps to simplify diagnostics regulatory approval through two draft guidance documents this year. The first draft guidance, ["Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibility Debilitating Diseases or Conditions"](#) streamlines the premarket approval (PMA) pathway for diagnostics that address unmet needs by allowing alternative study designs. The second guidance document, ["Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval"](#) allows smaller clinical studies for approval of diagnostics that address unmet medical needs, with the admission that smaller trials may leave more uncertainty about the risks or benefits of these tests. However, that uncertainty is preferable to a complete lack of diagnostics for certain infections where there is unmet medical need. Additional data can then be collected post-approval to provide additional information about the diagnostic's efficacy and appropriate utilization in real world settings. We encourage the Subcommittee to work with FDA to build on these efforts with a focus on providing a

feasible approval pathway for diagnostics that can rapidly identify pathogens causing infection and determine their resistance to antimicrobial drugs.

IDSA also thanks the Subcommittee for its efforts to craft and enact the Protecting Access to Medicare Act of 2014 (PAMA). We are particularly supportive of PAMA's provisions to improve diagnostic test reimbursement, and we view this new law as an excellent foundation on which to build future diagnostic reimbursement reform. IDSA looks forward to the new expert panel that PAMA requires the Secretary of Health and Human Services to establish on issues surrounding diagnostic tests. This expert panel will also provide input on reimbursement levels, temporary Current Procedural Terminology (CPT) code assignment for new diagnostic tests, and help develop policies to facilitate the appropriate use of diagnostic tests. We hope the Subcommittee will support our call for this panel to include infectious diseases physicians and scientists as well as clinical microbiologists to provide this necessary expertise. We also encourage the Subcommittee to conduct oversight, as needed, to ensure prompt and appropriate implementation of the diagnostics reimbursement provisions in PAMA. Specifically, IDSA recommends that reimbursement cover the cost of testing, at a minimum; that wide regional variations in reimbursement for diagnostic testing be eliminated; and that the process of assigning new CPT codes for diagnostic tests be simplified, expedited and made more transparent.

Additional research is also needed to understand more fully the impact of diagnostics. While we recognize that innovative infectious diseases diagnostic tests can have a significant impact on patient outcomes, public health, and health care resources utilization, we lack sufficient concrete

data to inform and demonstrate these points. We urge the Subcommittee to explore ways to encourage the conduct of outcomes research to provide data on diagnostic use in varied clinical settings and the effect of diagnostic testing on patients, public health and the health care system. With strong supporting data, clinicians can be educated about the utility and optimal use of new tests, increasing their rate of integration and appropriate use within the health care community. The Patient Centered Outcomes Research Institute (PCORI) is well positioned to support the evaluation of clinical outcomes of new diagnostics, but to date, PCORI has focused largely on chronic conditions rather than infectious diseases. IDSA also urges the Subcommittee to explore opportunities for the Agency for Healthcare Research and Quality (AHRQ) and the Health Resources and Services Administration (HRSA) to assist health care institutions and professional societies with educational programs about the utility of infectious diseases diagnostic tests.

Once again, IDSA sincerely appreciates the Subcommittee's continued dedication to addressing the public health crisis of antibiotic resistance and the urgent need for new antibiotics and diagnostics. We look forward to opportunities to work with the Subcommittee to advance our common policy goals to improve patient care and public health and save lives.