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COVID-19 VACCINE CLINICAL TRIAL CONCERNS

Announcements have been made that Moderna, the University of Oxford and AstraZeneca, and Johnson & Johnson independently of one another will begin testing proposed coronavirus vaccines in stage three trials beginning in July 2020. Related to the important matter of whether these attempts or any related investigations will yield products that protect against the onset of COVID-19 is the essential question of which kinds of individuals will benefit from this research. Key demographic characteristics, such as age, gender, and race/ethnicity help to distinguish one person from another. Unless the pool of participants in these clinical trials adequately reflects such differences, then the overall impact of any vaccine may be limited to representatives of groups taking part in such studies.

Major shortcomings presently exist in the composition of participants in clinical trials. As reported in the March 2020 issue of the journal *Contemporary Clinical Trials Communications*, adult participation in U.S. cancer clinical trials is at less than 10% of cancer patients, with even lower rates for racial and ethnic minority groups. For example, African Americans comprise 5% of patients enrolled in trials that support FDA approval of new drugs, while representing 13.3% of the general U.S. population. Cancer is the leading cause of death for Asian Americans, yet they comprise just 3% of cancer participants in clinical trials. Also, Hispanics represent less than 3% of participants in similar investigations, despite accounting for an estimated 17.8% of the U.S. population.

An under-representation of older adults in cancer clinical trials remains an ongoing concern. Consequently, optimal treatment in this group remains undefined. The January 2020 issue of the *Journal of Geriatric Oncology* describes challenges involving efforts to increase their level of participation. Older adult cancer patients, differ from younger adults since they often possess more comorbidities, take more medications, and have diminishing organ function, which often excludes them from clinical investigations. Furthermore, older adults enrolled in studies tend to be fitter and healthier than the average older patient seen in clinics, which leads to uncertainty about the risks, benefits, and tolerability of systemic therapies in the older population.

Potential barriers to enrollment of older adults in trials have been identified. One reason for non-accrual of older adults is due to trial unavailability or patient ineligibility. Strict exclusion criteria, especially those related to functional status, organ function, and comorbidities, which are common in older patients, can serve as major enrollment barriers.

Mortality data for victims of the COVID-19 epidemic show that some portions of the U.S. population have been devastated more than other demographic segments. Patients 80 years of age and older residing in long-term care facilities have been particularly hard hit. African American males also have died at significantly higher rates than their proportion of the population would suggest. Thus, it would be most prudent to ensure that stage three vaccine trials represent these groups adequately.

PRESIDENT'S CORNER

BY ASAHP PRESIDENT PHYLLIS KING

Leadership During Change



Higher education is in the midst of transformational change due to the pandemic. It has been experiencing pressures to change for some time now. The pandemic has just accelerated and significantly disrupted any sense of tradition activity. Leaders have had to react and recover, and now must reinvent their future as the political, economic, social and cultural ramifications of this disruption become known. Universities are forming partnerships, restructuring campus units, consolidating programs, and elevating the importance of their teaching and learning center and IT departments to adapt to new ways of learning.

Whether you are a program director, department chair, or dean, the recent confluence of events is testing your leadership like never before. Common advice for leaders during this time is to first and foremost make health and safety the top priority for everyone. Engaging parties from all units on campus in strategic planning should include staying true to your mission, protecting the health and safety of students and employees, and adopting flexibility, creativity and adaptability as means of preserving your future.

Leaders can help their teams with transition by working with campus administration to clarify the vision and establish structures that support change. It is important to keep the whole college and campus in mind when making changes as actions taken in one program or department can affect the entire college and campus. Feedback on proposed changes should come from both inside and outside of the university to reach various stakeholders and receive diverse perspectives from which to make better informed decisions.

In order to get the support of those affected by change, the rationale or purpose of the change must be clearly conveyed. Clear, open, authentic and consistent communication is key to earning support for change from others. This can be done through multiple channels including email, teleconferencing, newsletters, etc. Encouraging questions and feedback indicates a leader's receptiveness to listening and understanding others' viewpoints.

Modeling a positive response to organizational change and conveying trust in campus leadership can also provide additional assurance to your team that change is being handled with competence. For more insights on leadership during change, I encourage you to use your ASAHP membership network, attend ASAHP's ongoing webinars, join ASAHP's online communities, and watch for a series of upcoming virtual presentations on current topics.

"Be the Change You Want to See in the World" ... Mahatma Gandhi

EFFECTIVE CORONAVIRUS MESSAGES FROM ACADEMIC INSTITUTIONS

Students and their families eagerly await messages from colleges and universities. The firm Eduventures conducts a *Student Sentiment Survey* annually to understand better how college-bound high school students research colleges and how they perceive institutional recruitment outreach. This year's data include responses from 6,100 high school seniors, juniors, and sophomores across the nation. Respondents were asked whether they recalled a school that communicated particularly well during the crisis, and if so, what that communication entailed. Sixty-eight percent of seniors had positive experiences with institutional COVID-19 messaging. The top five communicators based on frequency and consistency of mention are listed in no particular order as follows:

Alvernia University
 Prairie View A&M University
 Southern Utah University
 Oregon State University
 University of Texas Rio Grande Valley



CONGRESS IN A TIME OF CORONAVIRUS

A presidential election year can produce distortions in how Congress normally functions. The party in control of the White House typically stands to benefit in an election year from the passage of legislation that is popular with the electorate. Developments of that nature furnish a rationale for proclaiming why it is imperative that the political party in power remain in that position to ensure that good times continue to roll forward. The opposition party views the situation quite differently, finding it more convenient to prevent the passage of progressive legislation. That stance enables them to point an accusative finger at incumbents as being ineffective in accomplishing what is necessary. Their rationale is that it is high time for positive changes to occur and they inform the electorate in loud and clear terms that they are the political party with the ability to achieve desirable outcomes.

The year 2020 is proving to be vastly different. A main reason is that COVID-19 persists in being a major concern as of the end of June. As lockdowns have been loosened around the U.S., new cases of this disease continue to appear and hospitalizations are on the rise. Additional remedies are sought and can be implemented, but it is patently clear that agreements of a bipartisan nature are required. A recent example of a willingness to work cooperatively is a letter by a bipartisan group of 30 U.S. senators that was sent on June 15 to Majority Leader **Mitch McConnell (R-KY)** and Minority Leader **Charles Schumer (D-NY)**, asking them to make permanent certain provisions from the bipartisan CONNECT for Health Act that were included in previous COVID-19 legislation. These provisions led to an important expansion of access to telehealth services for Medicare beneficiaries during the pandemic.

The reason for advocating increased access to telehealth stems from its potential to expand availability of health care, reduce costs, and improve health outcomes. Telehealth has proven to be pivotal for many patients during the current pandemic, ensuring that they receive the care they need while reducing the risk of infection and the further spread of COVID-19. Expanded Medicare coverage of telehealth services on a permanent basis, where clinically appropriate and with appropriate guardrails and beneficiary protections in place, would ensure that telehealth continues to be an option for all Medicare beneficiaries after the pandemic ends.

Supporters of this initiative believe that the population has benefited significantly from this expansion of telehealth and have come to rely on its availability. They stress that Congress should expand access to telehealth services on a permanent basis so that telehealth remains an option for all Medicare beneficiaries both now and after the pandemic. Doing so would assure patients that their care will not be interrupted when the pandemic ends. It also would provide certainty to health care providers that the costs to prepare for and use telehealth would be a sound long-term investment.

Apart from telehealth, other major decisions are pending on the near horizon. One of them has to do with deciding if a federal supplemental unemployment benefit of \$600 per month should be extended beyond July 31 when it is scheduled to end. From a health professions workforce standpoint, S. 3993 is a bill introduced in the Senate on June 17 to permit a licensed health care provider to offer health care services to individuals in one or more States in which the provider is not licensed.

2020 ASSOCIATION CALENDAR OF EVENTS

July 10, 2020—Virtual Abstract Presentations Submission Deadline

October 28-30, 2020—ASAHP Annual Conference in Long Beach, CA **Cancelled**

HEALTH REFORM DEVELOPMENTS

The appearance of COVID-19 in the United States has had a major impact on the nation's health care delivery system. Lockdowns in many states are viewed as being successful in slowing down the rate at which new cases of the disease occur. Now that such restrictions have been loosened, in many jurisdictions there is a resurgence in the number of new cases as businesses reopen and some individuals choose to refrain from wearing masks when in public settings. The number of hospital admissions continues to grow in certain states, heightening a concern that the ability to treat newly infected patients may be compromised if hospital facilities become sufficiently overwhelmed.

Older Americans are disproportionately affected by this disease. Data released by the Centers for Medicare & Medicaid Services (CMS) on June 22, 2020 show that more than 325,000 Medicare beneficiaries had a diagnosis of COVID-19 between January 1 and May 16 of this year, which translates to 518 COVID-19 cases per 100,000 beneficiaries. The data also indicate that nearly 110,000 beneficiaries were hospitalized for COVID-19-related treatment, which equals 175 COVID-19 hospitalizations per 100,000 beneficiaries. Blacks were hospitalized with COVID-19 at a rate nearly four times higher than whites. Disparities go beyond race/ethnicity and suggest the impact of social determinants of health, particularly socio-economic status. End-stage renal disease (ESRD) patients (individuals with chronic kidney disease undergoing dialysis) had the highest rate of hospitalization among all Medicare beneficiaries, with 1,341 hospitalizations per 100,000 beneficiaries. These patients also are more likely to have chronic comorbidities associated with increased COVID-19 complications and hospitalization, such as diabetes and heart failure.

Medicare And The Health Care Delivery System

The Medicare Payment Advisory Commission's *June 2020 Report to the Congress: Medicare and the Health Care Delivery System* was issued on June 15, 2020. The Commission believes that unless substantial changes are made to the way Medicare pays for services and to how beneficiary care is organized and delivered, the cost of the Medicare program will remain on an unsustainable trajectory. The Part A trust fund is projected to exhaust its reserves in 2026, which will force Medicare to reduce payment rates sharply for hospitals and other Part A providers unless policymakers take some other action. The Commission asserts that the use of fee-for-service payment for Medicare services should be replaced, over time and to the degree feasible, by payment to accountable systems of care that have incentives to: provide preventive services and early disease detection, improve the quality and beneficiary experience of care; avoid delivering unnecessary or inappropriate services; control the costs of providing necessary services in the most appropriate care setting; deliver chronic care services through care coordination among providers; coordinate both the medical and nonmedical needs of beneficiaries; and enhance the use of technologies that improve quality and reduce program costs. Moreover, serious attention must be given to new innovations, for example, changing how hospitals are paid and giving providers incentives to manage the cost of medications.

Report To Congress On Medicaid And CHIP

The Medicaid program was instrumental in providing coverage to the uninsured when the Patient Protection and Affordable Care Act became law in 2010. Medicaid is playing this same role during the COVID-19 pandemic. Unemployment that results in loss of health insurance coverage through one's job has helped to fuel a surge in the rolls of Medicaid beneficiaries. The Medicaid and CHIP Payment and Access Commission (MACPAC) on June 15, 2020 submitted its *June 2020 Report to Congress on Medicaid and CHIP*. This document contains six chapters addressing three fundamental challenges facing Medicaid: (1) improving integration of care for low-income seniors and individuals with disabilities who are dually eligible for Medicaid and Medicare; (2) ensuring that Medicaid is the payer of last resort when beneficiaries also have coverage from another insurance program; and (3) addressing concerns about high rates of maternal morbidity and mortality. A focus is on integrating Medicaid and Medicare, two separate programs that were not designed to work together, for beneficiaries who are eligible for both entities. Dually eligible beneficiaries account for a disproportionate share of Medicaid and Medicare service use and spending. Integrating the delivery and financing of their care is viewed as having a potential to address better the totality of their needs and reduce spending.

DEVELOPMENTS IN HIGHER EDUCATION

As summer moves forward, administrators of academic institutions at all levels continue to be plagued by doubts and uncertainties regarding whether schools should be reopened and students readmitted in coming months. When infections occur, youth cohorts have not been affected as drastically by COVID-19 in comparison to adult groups, especially patients 80 years of age and older. Nonetheless, once infected, even if asymptotically, students have the potential to transmit this deadly disease to adults with whom they come in contact, such as teachers, and older relatives. A significant unknown is the extent to which parents are willing to have their offspring attend school as long as there is a perceived threat of infection.

What Will The College Football Season Look Like This Year?

Many colleges, and even high schools, depend on financial support derived from athletics. College football is a bountiful source of revenue as evidenced by stadiums that seat more than 100,000 fans who not only buy tickets, but even spend generously on concessions. Enlightened officials at some institutions have seen the value of adding alcoholic beverages to what is sold to patrons as a means of enhancing the amount of money flowing into school coffers. Players already are in training on some campuses and reports indicate that some of them are testing positive for the coronavirus. Although many are in superb physical condition, it is not uncommon for offensive and defensive linemen who weigh more than 300 pounds to be classified officially as being obese, a condition that has contributed to mortality outcomes among other segments of the population with this condition who became infected. Given the airborne capability of the coronavirus to be transmitted over a considerable distance by screaming fans at these events, a challenge is presented in figuring out how to adjust social distancing patterns safely in arenas. Fewer seats that are filled also can exert a negative impact on revenues.

Institutions Are Unequal In their Ability To Withstand Revenue Shortfalls

Apart from any health dangers posed by the presence of the appearance of a deadly infections disease on school grounds, there can be severe financial consequences for failing to reopen some academic institutions. Publicly-funded schools are somewhat shielded from hazards associated with reductions in tuition income and student fee revenues, but the same cannot be said of their counterparts in the private realm. Prior to the appearance of the coronavirus, many states already were reeling financially because of increased pressures arising from growing expenditures in their Medicaid programs. As job losses began occurring on a massive scale in the U.S. beginning in March of this year, that economic contraction typically was accompanied by cancellations of health insurance coverage that is connected to employment status. Individuals so affected by losing their health insurance now have to rely on Medicaid coverage, which adds to the financial woes of many states that will find it increasingly difficult to devote resources to an ailing educational sector. Moreover, a related concern is that revenue obtained through fund raising and philanthropic contributions may not be as robust as it has been previously.

Rethinking Accreditation And Quality Assurance

The past several years have been characterized by a shared sense that current quality review needs to be reimagined to serve students and society more effectively. **Judith Eaton**, President of the Council for Higher Education Accreditation (CHEA), expressed her thoughts on this matter in June 2020 by identifying five specific steps that can lead to reinventing a review of quality in higher education, a post-Covid redesign of accreditation and quality assurance that, if effective, will establish a foundation for the next era of these important efforts. Accreditation and quality assurance are needed that capture quality, while embracing new providers and creatively using technology that brings students greater opportunity, access, and progress in furthering their education. The five steps are:

- Sustain the fundamental value commitments of higher education
- Expand the range of activity and scrutiny of quality review
- Modify the primary purposes of accreditation and quality assurance
- Enlarge the universe of accreditation/quality assurance providers themselves
- Redesign the accreditation/quality assurance review process

QUICK STAT (SHORT, TIMELY, AND TOPICAL)

Prevalence Of Tooth Loss Among Older Adults, 2015-2018

A June 2020 *Data Brief* from the National Center for Health Statistics (NCHS) indicates that the prevalence of complete tooth loss among adults aged 65 and over was 12.9% and increased with age: 8.9% (ages 65–69), 10.6% (ages 70–74), and 17.8% (ages 75 and over). Non-Hispanic black older adults (25.4%) had a higher prevalence of complete tooth loss than Hispanic (15.3%) and non-Hispanic white (10.9%) older adults. Prevalence of complete tooth loss was higher for older adults with less than a high school education (31.9%) compared with those with a high school education or greater (9.5%). From 1999–2000 through 2017–2018, the age-adjusted prevalence of complete tooth loss among all older adults declined significantly. Nevertheless, complete tooth loss can diminish quality of life by limiting food choices and impeding social interaction. Reducing this problem is a national health goal monitored by *Healthy People*.

Opioid-Involved Emergency Department Visits, Hospitalizations, And Deaths

A *National Health Statistics Report* on June 16, 2020 reveals that in the 2014 National Hospital Care Survey (NHCS), there were 15,495 patients with an opioid-involved ED-only visit and 24,059 patients with an opioid-involved hospitalization. Of the patients with an opioid-involved hospitalization, 1,805 died (9%) within one year of discharge. Of these deaths, 341 (19%) resulted from a drug overdose. Opioids most frequently mentioned included heroin (46%), fentanyl (20%), oxycodone (13%), methadone (12%), and morphine (12%). These categories are not mutually exclusive because a death may involve more than one drug. For approximately 22% of patients who died of an opioid-involved drug overdose in 2014, their last ED-only visit or hospitalization was opioid-involved. While lockdowns stemming from COVID-19 are aimed at preventing fatal infections, a concern is that social isolation may lead to increases in drug overdoses, suicides, and other health problems. Future studies will uncover the extent of such occurrences.

HEALTH TECHNOLOGY CORNER

Personalized Mapping Of Drug Metabolism By The Human Gut Microbiome

Previous studies have examined how single species of gut bacteria can metabolize oral medications, but a new framework enables the evaluation of an individual's entire intestinal microbial community at once. A research team at Princeton University used an approach to evaluate the gut microbiome's effect on hundreds of common medications already on the market by indicating how the microbial community in the intestines can chemically transform, or metabolize, oral medications in ways that have an impact on safety and efficacy. According to a study published on June 10, 2020 in the journal *Cell*, researchers identified 57 cases in which gut bacteria can alter existing oral medications. Eighty percent of those had not been previously reported, emphasizing the potential of the method for revealing unknown drug-microbiome interactions. The new methodology could aid the development of medications that are more effective, have fewer side effects, and are personalized to an individual's microbiome.

Magnetolectric Materials For Miniature, Wireless Neural Stimulation At Therapeutic Frequencies

A major challenge for miniature bioelectronics is wireless power delivery deep inside the body. Electromagnetic or ultrasound waves suffer from absorption and impedance mismatches at biological interfaces. Magnetic fields do not suffer these losses, which has led to magnetically powered bioelectronic implants based on induction or magnetothermal effects. These approaches have yet to produce, however, a miniature stimulator that operates at clinically relevant high frequencies. A manuscript published on June 8, 2020 in the journal *Neuron* describes study results suggesting that using magnetolectric materials for wireless power delivery is more than a novel idea. These materials are viewed as being excellent candidates for clinical-grade, wireless bioelectronics. Tiny implants capable of modulating activity of the brain and nervous system could have wide-ranging implications and could be useful for treating depression, obsessive-compulsive disorders and more than a third of patients who suffer from chronic, intractable pain that often leads to anxiety, depression and opioid addiction.

AVAILABLE RESOURCES ACCESSIBLE ELECTRONICALLY

Advancing Adolescent Flourishing: Moving Policy Upstream

A new report, *Advancing Adolescent Flourishing: Moving Policy Upstream*, on teen well-being in the U.S. finds that 60% of those ages 13-18 are not thriving, which is defined as experiencing positive emotions as well as positive emotional and social functioning. Teens also are reporting higher stress levels than older adults, the majority of which is due to mass shootings, concern about peers with anxiety and depression, and rising suicide rates. Majorities of teens also have been discriminated against, and almost all report hearing the word "gay" used disparagingly at school. The report identifies 47 action items that policymakers at local, state, and national levels can take to improve the well-being of teens. These items range from engaging with social media platforms and influencers to promote more content that encourages teens to spend time helping others in their community to encouraging lawmakers to design budgets with teenage well-being in mind. Enhanced teen-focused health policies at local, state, and federal levels of government will contribute greatly to the larger enterprise of healing the nation for all. Yet, current national investment in adolescents is lacking. The analysis includes action items and recommendations that are promising for advancing teen psychological, social, and emotional well-being. The report can be obtained at <https://wellbeingtrust.org/wp-content/uploads/2020/06/AdvancingTeenFlourishingFinalReport.pdf>.

Preparing For The Next Pandemic

U.S. Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman **Lamar Alexander (R-TN)** released a White Paper, *Preparing For The Next Pandemic*, on June 9, 2020 that calls for public comment on five recommended areas for near-term congressional action to learn from the COVID-19 response and better prepare for future pandemics. He noted in an executive summary that "In the midst of responding to COVID-19, the United States Congress should take stock now of what parts of the local, state, and federal response worked, what could work better and how, and be prepared to pass legislation this year to better prepare for the next pandemic, which will surely come." He outlined five main recommendations to improve the country's preparation for future pandemics:

- Accelerating research and development of tests, treatments, and vaccines.
- Enhancing disease surveillance.
- Addressing federal and state stockpiles, distribution, and surge capacity.
- Improving state and local public health capabilities.
- Improving coordination of federal agencies.

The White Paper can be obtained at https://www.alexander.senate.gov/public/_cache/files/0b0ca611-05c0-4555-97a1-5dfd3fa2efa4/preparing-for-the-next-pandemic.pdf.

New Data On Community Resilience

Community resilience is the capacity of individuals and households within a community to absorb, endure, and recover from the impacts of a disaster. The U.S. Census Bureau on June 22, 2020 released the *Community Resilience Estimates* to measure the ability of a population to be successful in responding to situations that include weather-related and disease-related hazard events such as COVID-19. Estimates are based on information on individuals and households from the 2018 American Community Survey (ACS), the Census Bureau's Population Estimates Program, and National Health Interview Survey (NHIS) data. A tool showing risk level by state, county, and tract can be obtained at https://www.census.gov/data/experimental-data-products/community-resilience-estimates.html?utm_campaign=&utm_content=&utm_medium=email&utm_source=govdelivery.

NIH FUNDING AND THE PURSUIT OF EDGE SCIENCE

With an annual budget of more than \$37 billion, the National Institutes of Health (NIH) plays a critical role in funding scientific endeavors in biomedicine. Funding innovative science is an essential element of the NIH's mission, but the ability to fulfill this aim has been questioned. Based on an analysis of a comprehensive corpus of published biomedical research articles (more than 24,000,000 of them in the MEDLINE database), a study was conducted to measure whether the NIH succeeds in funding work with novel ideas, referred to as "edge science." The results are described in the June 2, 2020 issue of the journal *Proceedings of the National Academy of Sciences of the USA*. As background, it may be worth noting that both scientific and political considerations may lead the NIH to underfund trying out new ideas. First, because the NIH visibly spends public money, it needs to show discrete manifestations of improvements in health, as well as technological breakthroughs, arising from its supported research. This consideration can lead to a preference to support ideas that already have shown promise, rather than edge science. Second, NIH scientific review panels, for reasons related to their constitution, tend to reward projects that evidently are feasible over novel projects.

This investigation shows that edge science is more often NIH-funded than less novel science, but with a delay. Papers that build on more recent ideas are NIH-funded less often than are papers that build on ideas that have had a chance to mature for at least seven years. Three key findings are: First, the tendency to fund edge science is limited mostly to basic science. Papers that build on novel clinical ideas are not more often NIH-funded than are papers that build on well-established clinical knowledge. Second, novel papers tend to be NIH-funded more often because there are more NIH-funded papers in innovative areas of investigation, rather than because the NIH funds innovative papers within research areas. Third, the NIH's tendency to have funded papers that build on the most recent advances has declined over time. In this regard, NIH funding has become more conservative despite initiatives to increase funding for innovative projects. Given the focus in this particular study on published papers, the findings reflect both the funding preferences of the NIH and the composition of the applications it receives.

TRANSHUMANISM AND THE PROSPECT OF NEVER HAVING TO DIE

Each passing day furnishes new evidence that the coronavirus has not yet fully completed its grim work of increasing the human ranks of the dearly departed. How refreshing then to come upon an article in the June 20-21, 2020 weekend edition of *The Wall Street Journal* that discusses optimistic views on the topic of *transhumanism*, the idea of using technology to overcome sickness and aging. Financial support for life-extension research has been provided by well-heeled investors as optimism abounds in some quarters that not only is it possible to live to the ripe age of 500, a time may arrive when individuals in middle age may have a fair chance of never dying. Starting with the premise that transhumanism promises that death can be conquered physically, not just spiritually, it appeared worth an effort to go to the professional literature to assess what progress is being made in achieving such lofty outcomes.

If an article appearing in May 2020 in the journal *Clinical and Translational Science* can be viewed as a reliably authoritative source for current thinking on such matters, then despite regenerative medicine (RM) being one of the hottest topics in biotechnology for the past three decades, it generally is acknowledged that the field's performance at the bedside has been somewhat disappointing. RM is seen as having had an undeniable positive influence on the process of bench to bedside research. Preclinically, it has helped identify limitations of evidence-based medicine and contributed to the paradigm shift to the trial-and-error method. If the translation of RM therapies is to be improved, however, many challenges to be overcome lie in the early stages of therapy development, such as identifying mechanism(s) of action, validating preclinical experimental models, and incentivizing translational research for basic scientists. Regulatory changes have been made in later stages, but much still needs to be addressed, such as adoption of clinical trials that are more rigorous and include long-term follow-up studies; development of appropriate manufacturing technology; synchronization of regulatory agencies, and a clear plan for reimbursement strategies.