December 2016 - ISSUE 12

WKMJ

World Korean Medical Journal

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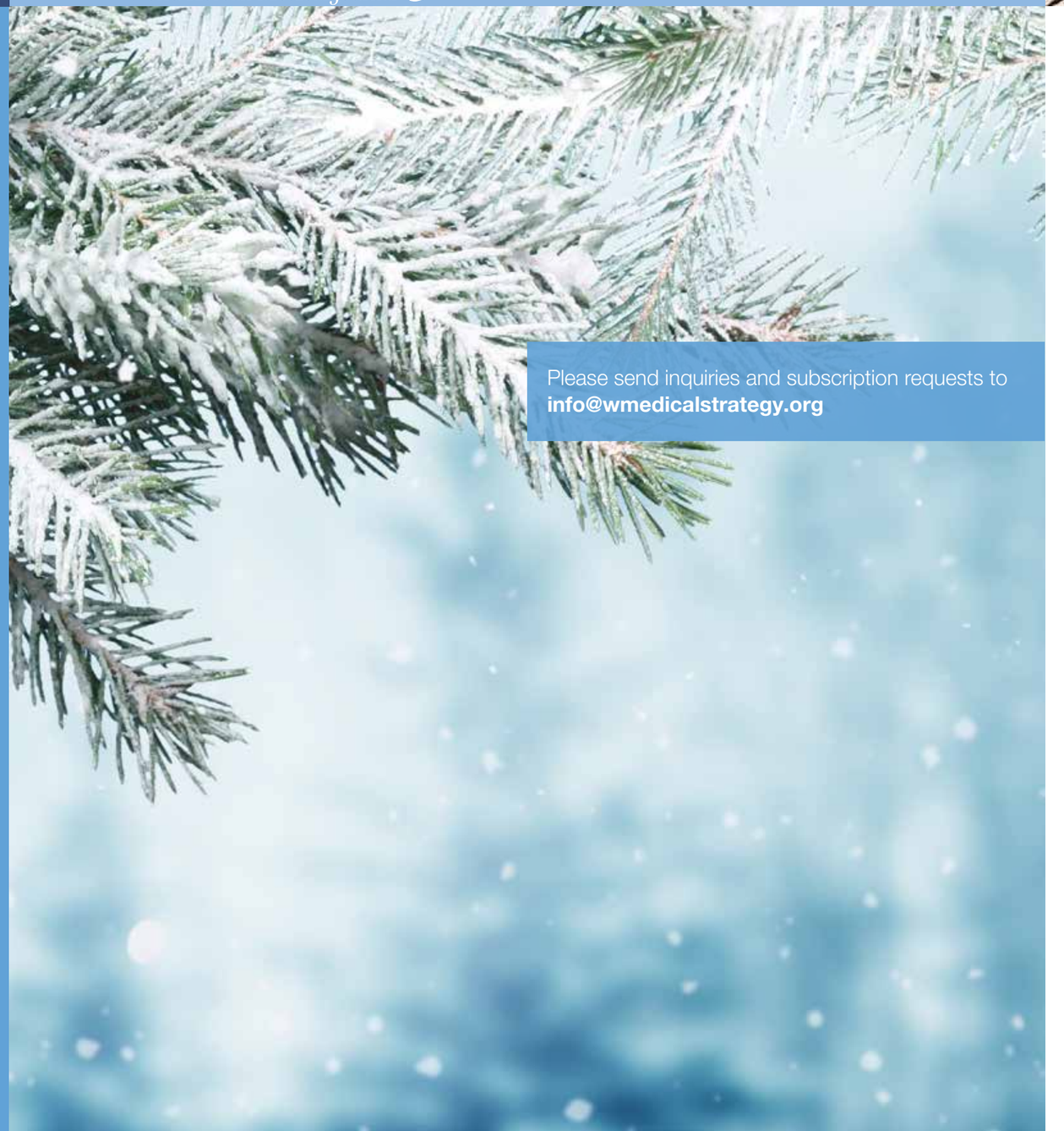

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In Memory of Dr. Sammy Lee, WKMJ's First Inspirational Healthcare Leader

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FROM THE PUBLISHER

Dear Colleagues,

As one reflects on the year 2016, some will remember it as a transformative time period in history. Political happenings in the US and Korea are heralding big changes, and it will affect healthcare industry as well. Obama had changed healthcare sector in the US with the Affordable Care Act (ACA). The ACA, for those outside the US, was a movement to require more people to have health insurance for benefit of those who did not receive proper healthcare and also to healthcare providers and their related services by providing medical reimbursement system. The new administration wants to "repeal" ACA so less people, especially the lower socioeconomic class, will have coverage for healthcare. The future is uncertain with many changes to come.

In the 12th issue of WKMJ, we interviewed Dr. Waun Ki Hong, who is a very prominent Korean American physician with a long distinguished career and achievements. Dr. Hong has been involved in cancer care and research since the US government declared War on Cancer in the 1970's by President Nixon. He was at the preeminent oncology institution in the world, MD Anderson, where he has had prominent leadership role. Dr. Hong's accomplishments are numerous and his fostering the next generation of researchers will lead to further breakthroughs in the War on Cancer. The War on Cancer has not been won yet, but many battles have lead to victories.

The entrepreneur interview is with Mark Paxton of Rx-360, an international nonprofit consortium with the aim of improving patient safety by sharing information and developing processes to improve the integrity of the healthcare supply chain. As supply sources and chains become more international, the delivery of healthcare products requires quality assessments in every step and must be cost effective through economies of scale. The Rx-360 is dedicated in evaluating all angles to develop and implement quality systems as well as opportunities for cost savings.

In closing, I would like to memorialize the greatest physician and athlete Dr. Sammy Lee, who competed in two Olympics and won 2 Gold and 1 Silver medals in diving for the US and was featured in the first issue of WKMJ. In addition, World Korean Medical Organization had a busy 2016 with meetings in Seoul, Korea and at US Congress in Washington DC. We look forward to another great year and I would like to wish all a Happy Holidays and Happy New Year.

David Y. Ko, MD
Publisher
President of WKMO
Keck School of Medicine of USC

FROM THE EDITOR-IN-CHIEF

As TIME magazine put it, "one of the most shocking U.S. elections in modern political history", Mr. Donald Trump has defeated Secretary Hillary Clinton in 2016 US presidential election. During his campaign, Mr. Trump has promised many things such as 'building a wall along the border of Mexico', 'repealing the Affordable Care Act', 'renegotiating NAFTA' and a lot more. His election, coupled with Republican sweep of Washington also generated a ton of enthusiasm for biotech and pharma industries. Stock prices for US biopharma companies have been up by 10% to 15% since the election. It reflected optimistic view from the industry that government drug price control will no longer be threat to the drug manufacturers. But, from his recent interview with the TIME magazine in December, Mr. Trump suggested that some stock analysts may have misread his intentions, and reassured his goal of bringing down drug prices. Since the innovation needs to be rewarded, raising prices of new drugs cannot always be criticized. Nonetheless, patients' affordability and accessibility also need to be weighed as same importance as rewarding innovators, because therapeutic products and technologies deal with lives of human beings.

Through the 12th edition of WKMJ, we have interviewed a physician leader in therapeutic world, who has brought both innovation and accessibility of cancer treatments to the world. Dr. Waun Ki Hong is the Head of Division of Cancer Medicine at the University of Texas MD Anderson Cancer Center, Houston, Texas and also the past president of the American Association for Cancer Research (AACR). Dr. Hong shared his story and insight with our readers, and told us his great passion, devotion and success he had established throughout his career in cancer researches. Dr. Hong had been the greatest role model for Korean American physicians and younger generations as well as among medical researchers.

For the Entrepreneur Interview, we featured Mr. Mark Paxton, CEO of Rx-360, International Pharmaceutical Supply Chain Consortium, an organization which deals with the hottest topic of the pharma industry, supply chain management. I have long history of personal and professional relationship with Mark over decades, through the Asia Pacific Economy Cooperation (APEC) activities, APEC Harmonization Center, Regulatory Harmonization Institute (RHI), Columbus Project, and more. Mark was my partner with the role of Executive Vice President when I launched W Medical Strategy Group in 2014. I always enjoyed his expertise, insights, great personality, and friendship. I am glad to share his story with our readers.

Addition to these two major articles, we have rich selection of articles which will bring amusement of reading to our readers. World Korean Medical Journal is currently seeking an innovative step forward by conducting a project to enhance its contents and expand readership.
You will meet with a whole new WKMJ from the editions of 2017.

Thank you.

DoHyun Cho, PhD
Editor in Chief
President & CEO of W Medical Strategy Group
Chairman of New York Health Forum

WKMJ RECAP OF THE LAST ISSUE

Cover Story

Inspirational Korean Healthcare Leader "Dr. Augustine M.K. Choi, Chairman of the Department of Medicine at Weill Cornell Medical College"

Dr. Augustine M.K Choi is the Chairman of the Department of Medicine at Weill Cornell Medical College and Physician-in-Chief at New York Presbyterian/ Weill Cornell Medical Center. Dr. Choi is also the Parker B. Francis Professor of Medicine at Harvard Medical School and chief of pulmonary and critical care medicine at Brigham and Women's hospital in Boston. He is a clinician-scientist with expertise in the pathology and biology of lung disease. To read more about Dr.Choi's clinical researches and how his leadership impacted research landscape, please read issue 11.

Entrepreneur Interview

Dr. Leon Reyfman, Chief Executive Officer at Advanced Clinical Laboratory Solutions, Inc

Dr. Reyfman, the Chief Executive officer at ACLS is board-certified in Anesthesiology and pain management. He serves as director in Interventional Pain Medicine at Long Island College Hospital and is assistant clinical professor of Anesthesiology at SUNY Downstate Medical School. ACLS is a rapidly growing laboratory testing company offering toxicology and pharmacogenetics testing services. To learn more about entrepreneurial physician who leads fight against drug epidemic, please refer to issue 11.

Biopharmaceutical Report I

FDA Review Policies for PD-1/PD-L1 Inhibitors Spark Expert Debate

The FDA may choose to become more critical on reviews and require larger studies for approval, or require longer-term monitoring and stronger label warnings. Whilst the FDA won't change its overall policy, it's possible me-too PD-1/PD-L1 inhibitors may no longer qualify for the FDA's breakthrough designation or for accelerated approval. To find out more, please read issue 11.

Biopharmaceutical Report II

Democratizing Antibodies

With the goal of expanding access to antibody-based drugs worldwide, the Bill & Melinda Gates Foundation is turning to industry to innovate its methods of manufacturing the proteins. Previously, the organization signed deals with Biogen Inc. and Just Biotherapeutics Inc., fostering programs to reduce costs and increase yields that benefit both the for-profit and not-for profit enterprises. To learn more about how organizations try to improve antibody production, please refer to issue 11.

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INSPIRATIONAL KOREAN HEALTHCARE LEADER

Dr. Waun Ki Hong, Division Head of Cancer Medicine at The University of Texas MD Anderson Cancer Center

COVER STORY

1. Dr. Hong, you are a world-renowned successful medical oncologist. What was the reason for attending medical school? What motivated you to become a doctor?

- Entering medical school was very competitive even in the old days. I was admitted to Yonsei School of Medicine in Seoul, South Korea in 1960. My oldest brother, Dr. Suk Ki Hong, was one of the best Scientist in Korea. He is a brilliant scientist and he has been my role model throughout my life. He was the Chairman of Physiology Department in Yonsei Medical School and later on he became the Chairman of Physiology Department in the University of Hawaii before he moved to SUNY Buffalo. I was immensely inspired by him to enter medical school but at that time, I didn't know much about oncology. When I was receiving medical residency training in Boston VA Medical Center, I saw so many patients who were suffering from incurable cancer and it inspired me to pursue medical oncology training in Memorial Sloan Kettering Cancer Center in 1973.

Dr. Waun Ki Hong during an interview

> "I saw so many patients who were suffering from incurable cancer and it inspired me to pursue medical oncology training"

2. As a national and international leader in medical oncology, you may have gone through various obstacles; can you share some of the most difficult moments during your career?

- I immigrated to US in 1970 and received medical training in New York City and Boston. I have been very fortunate to work with many wonderful people in my academic career, who helped me in great deal. I must admit that it was tremendously challenging to overcome cultural and language barriers in my early days in the US, but I always interpreted it as an opportunity to tackle. Not only did I work very hard, but I also tried my best to work with disciplines and accountability.

Dr. Waun Ki Hong with his fellows in 2013 graduation (University of Texas MD Anderson Cancer Center)

3. You've served as the past president of the American Association for Cancer Research (AACR) and you have been honored with AACR's 10th annual Margaret Foti Award for Leadership and Extraordinary Achievements. You have been recognized for bringing unprecedented advances in translational and clinical cancer researches throughout your career. Can you share with our readers some of the major achievements and outcomes you have accomplished during your professional life?

- In my humble opinion, whatever contributions I have made is basically tip of an iceberg. Nevertheless, I have been very fortunate to make very small contributions in my professional career that has been translated to the cancer patients. If I can highlight four areas of my contributions, they are as follows:

1) Laryngeal preservation approach by using induction chemotherapy and radiotherapy without sacrificing human voice box in patients with advanced laryngeal I cancer. I was very fortunate to be forefront in this field of research and this successful story served as a foundation of organ preservation approach in many other cancers such as breast cancer, anal cancer and bladder cancer as well.

2) Establishing principles of chemoprevention research that led to development of cancer interception strategy that now has a tremendous potential to prevent cancer before the cancer develops fully.

3) Our pioneering research of precision medicine in Lung cancer through so called BATTLE (Biomarker-integrated Approaches of Targeted Therapy for Lung Cancer Elimination) trial in MDACC that opened up a field of precision medicine trials like MATCH, MPACT trials nationwide.

4) Last but not least, I was fortunate enough to have an opportunity to train hundreds of medical oncologists and scientists worldwide to be the next generation of cancer researchers.

4. You've been appointed as the division head and professor at the University of Texas MD Anderson Cancer Center, an American Cancer Society professor, and a Samsung Distinguished University Chair in Cancer Medicine. What are your responsibilities and principles in leading one of the most comprehensive academic and clinical departments?

- I had great honor and privilege to serve as Head of Division of Cancer Medicine which is the largest division in MD Anderson Cancer Center. MD Anderson Cancer Center has been ranked as Number One Cancer Center in USA by the US News & World Report for 10 out of last 11 years. The job as the Head of Cancer Medicine was extremely challenging and also exciting at the same time. Overseeing 16 academic departments and the largest Fellowship Program in the country was really unprecedented opportunity. My main job was to provide impeccable care for nearly 10,000 new cancer patients annually and also overseeing research activities of 350 faculties and managing over 100 Million Research Grants.

My principles for managing such huge academic program were basically displaying integrity, accountability, respect transparency, passion, and hardworking ethics. I tried my best to be a role model for all faculty and trainees as well as all employees. Fortunately, I was able to carry out my job with honor and integrity over 14 years, which is the longest tenure as the Head of Cancer Medicine in MDACC. Perhaps this is the single most proud achievement I have ever made in my professional career, as a man who immigrated to this country in 1970 and not even being allowed to dream big.

Dr. Waun Ki Hong providing a congratulatory remark on opening ceremony of The 6th Sevrance-MD Anderson Cancer Center Joint Symposium

5. Dr. Hong, you have been honored with American Society of Clinical Oncology's 2016 Special Recognition Award for your groundbreaking research in treatment modalities. What are some of the current trends in cancer research? What do you forecast the major changes would be in the areas of cancer research and treatments in next five years?

- I have been a member of American Society of Clinical Oncology (ASCO) since 1975 and served in many important committees in ASCO including the Chair of Cancer Prevention and also I was elected to serve as the Board of Director. Because of my contributions to ASCO and also many achievements as Head of Cancer Medicine, especially training hundreds of postgraduate doctors and clinical fellows, I was very grateful to receive ASCO Special Recognition Award in 2016 at the annual meeting in Chicago.

I believe that this is an incredibly exciting time of cancer care and cancer research because there is tremendous progress of understanding basic biology of cancer that ultimately will be translated to clinical care through translational research. Future of cancer research is very bright because of the exciting opportunities to make huge impact of cancer care through innovative targeted therapies and immunotherapies.

In addition, there is a huge opportunity to make impact through screening and early detection and also opportunity to intercept cancer driver in early stages and premalignant lesions through chemo and/or immune prevention strategy before cancer develops fully.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Dr. Waun Ki Hong and his colleagues at MD Anderson Cancer Center

6. What would be your advice or comments for current medical students as well as those who aspire to become a doctor?

- My advice to medical students who want to either practice as a physician or become an academician is very simple. They have to work extraordinary hard with pride and integrity and also they have to be unselfish team player in whatever they engage in to earn respect from their peers. I am a strong believer of following the quote from Benjamin Franklin, “God helps those who help themselves.”

7. WKMJ has readers from more than 10 countries globally. Please share your final words with our readers.

- As far as cancer care is concerned, there is no boundary at all. Cancer is global problem not limited to US. One out of two in men and one out of three in women will develop cancer in their life time. To make impact we all have to work together as a team, without territories, to end cancer in our society. W

Waun Ki Hong, M.D., F.A.C.P., D.M.Sc.(Hon.)

Head, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center

Waun Ki Hong, M.D., F.A.C.P., D.M.Sc (Hon) is Division Head and Professor at The University of Texas MD Anderson Cancer Center, an American Cancer Society Professor, and a Samsung Distinguished University Chair in Cancer Medicine. A national and international leader in medical oncology, Dr. Hong is a foremost authority on the treatment and prevention of head and neck cancer and lung cancer. Dr. Hong has developed treatment approaches that have enabled thousands of laryngeal cancer patients to avoid radical surgery and enjoy a better quality of life, eradicating the cancer while preserving the ability to speak and swallow. Dr. Hong also is one of the founders of cancer chemoprevention and pioneered a new paradigm for cancer—the possibility that it can be prevented or delayed. Additionally, he was the main architect and principal investigator for BATTLE (Biomarker-integrated Approaches of Targeted Therapy for Lung Cancer Elimination), the first successful biopsy-driven trial in lung cancer. This formative work opened up a new paradigm of personalized cancer therapy in solid tumors. His expertise spans more than 36 years of unprecedented advances in translational and clinical cancer research. Dr. Hong has authored more than 660 scientific publications, edited 11 books, including Senior Editor of Holland-Frei Cancer Medicine Eighth Edition, and currently serves on the editorial boards of 6 scientific journals. He was one of the founding deputy editors of Clinical Cancer Research.

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Entrepreneur Interview

Mark Paxton, Chief Executive Officer at RX-360

Mr. Mark Paxton is providing a congratulatory remark on opening ceremony of Korea Healthcare Business Center in 2009 (The Korea Society, NYC)

1. Rx-360 is an international pharmaceutical supply chain consortium dedicated to protecting patient safety. Please explain Rx-360's strategies, mission, and activities to our readers.

Rx-360's mission is to promote patient safety by sharing information and developing processes to improve the integrity of healthcare supply chains and the quality of materials moving in those supply chains.
To meet this mission, Rx-360 has pioneered a joint audit program for upstream suppliers, downstream distributors and others that are engaged in moving materials and products in commerce that must be properly qualified by manufacturers. In doing so, we manage audits of raw materials and basic chemicals, packaging materials, excipients, active pharmaceutical ingredients, wholesalers and common carriers by multiple sponsors who are each blinded from each other. In this way, we can lower the cost of the audits to each sponsoring manufacturer while simultaneously reducing the increasing audit burden on their trading partners.

In addition to the joint audit program, we have developed multiple white papers covering best practices for securing the integrity over the entirety of supply chains. We do this through internal work groups that are comprised of subject matter experts from our member companies. They have done a terrific job covering a myriad of programs and at any given time, we may have up to 15 active work groups operating at various stages.

2. Your function and audit programs you offer are not only important for the patients but also for pharmaceutical companies as well. Can you explain about the benefits pharmaceutical companies would receive from working with Rx-360?

As noted above, the pharma companies benefit by sharing the costs of audits performed uncommon suppliers. They also are blinded from each other when they do so, so we can alleviate anti-competitive concerns that may otherwise exist. And since we use a single audit firm - British Standards Institution - the audits tend to be consistent and importantly, our footprint is global. We perform audits wherever the suppliers exist. In addition, once an audit report is finalized, we make them available for purchase by third-party firms that did not participate in the audit. Those revenues are then used to provide credits to the original sponsoring firms for that will offset the costs of future audits they need to perform - up to 100% of their original audit cost.

While there are clear benefits to finished product manufacturers, the benefits to the suppliers that are audited can be even more extensive. For suppliers that sell components and other materials to pharmaceutical and medical device companies, they are frequently under substantial pressure to allow audits to their customers as part of the customers' required vendor qualification programs. For suppliers that have hundreds of customers at a given site, the burden of audit requests is truly unsustainable. Consequently, our joint audit program helps alleviate that burden.

Finally, under the new EU rules requiring manufacturers to qualify wholesalers and common carriers before distributing their products, those firms provide services to literally thousands of manufacturers. Therefore, they will absolutely require a joint audit firm like ours, along with a very robust licensing program to third parties, since they simply cannot and will not be able to withstand the avalanche of audit requests coming their way.

Mr. Mark Paxton is moderating the panel discussion at the US-Korea Pharma CEO Forum in 2010 (NYC)

Mr. Mark Paxton is talking with Dr. Joe McMenamin and Dr. William Ventura at the opening ceremony of W Medical Strategy Group in 2014 (The Yale Club, NYC)

Mr. Mark Paxton is giving congratulatory remark on opening ceremony of W Medical Strategy Group in 2014 (The Yale Club, NYC)

3. We see that Rx-360 has partnered with BSI Supply Chain Solutions to lead its international joint audit program. Why is international business important and what benefits will companies overseas gain from working with Rx-360? Also, how many members do you currently have globally?

First, let me address the membership question. Currently, Rx-360 has about 65 members in the EU, USA, China, Japan, and India. We are really hoping that companies in Korea will join us. Our members are generic, branded, small and large. They are finished product manufacturers and suppliers to those manufacturers. We also have a number of software and related companies that provide support services to all our manufacturing members. The goal is to do what we can to promote patient safety. Our membership fees are very small by trade association standards and it gives employees of both small and large members to participate equally so that solutions can be developed that are pragmatic and meet everyone's needs - particularly the patients we are honored to serve.

Second, regarding the utilization of British Standards Institution (BSI) as a sole provider of audit services, they have a proven record on a global basis. They are well-known to regulatory authorities and, on the medical device side, are a notified body in the EU and are a third-party accredited audit firm by the US FDA Center for Devices and Radiological Health (CDRH) as part of CDRH's Medical Device Single Audit Program (MDSAP). In those capacities, BSI serves as "co-regulators" and its practices are routinely subject to regulatory inspections. Hence, we have great confidence in their abilities. It's also worth noting that BSI - the parent company of the BSI Supply Chain Solutions - is, like Rx-360 - a non-profit, so they understand that aspect of our organization and what we are trying to do for the industry. That said, please also note that when Rx-360 initiated our pioneering joint audit program, we originally used many audit firms. The thought was the more competition the better for pricing. While the audit firms were all excellent, we found that the costs weren't nearly as favorable to Rx-360, as many of those firms were regionally focused. Hence, we put out a Request for Proposals (RFPs) for our entire book of auditing business for a period of three years with the intent of at least getting consistency in our audit costs. BSI won that bid, and they have been a great partner.

Finally, in addressing the importance of international business and working with Rx-360, it is most noteworthy that our mission is to protect patients by ensuring quality of medical products and the integrity of the healthcare supply chains in which those products move. Our supply chains - from raw materials to manufacturing to patients - are complex and global. There is no single national regulatory authority that can regulate these supply chains. It is therefore up to us, as industry partners, to do the right thing by ensuring that our patients, whether in the USA, Korea, Africa, or anywhere else, are getting the quality medicines that they and their healthcare providers expect. If we, operating collectively as "industry", don't deliver on the promise of quality medicines and devices to patients - wherever they may be - then who will, and what are the consequences to our businesses? All I can say is that if you sell snake oil to a consumer, that consumer isn't coming back, but maybe a government will, and neither are going to be favorable conditions for our businesses in the long run. So let's get rid of that behavior, and let's get rid of it across the globe by being an inclusive, quality-driven organization that readily shares best practices with the rest of industry for patients' benefit.

4. As a CEO of Rx-360, what do you think is the most important issue in the healthcare industry?

Global delivery of medicines and devices that are KNOWN to be safe and effective. Healthcare providers expect that when they prescribe a therapeutic intervention to a patient, then it will work as expected. They neither know or care where it was manufactured. If that intervention doesn't work, they will try another one. The fact that the first intervention didn't work because of quality-related problems because it was substandard or even counterfeited, is not usually on their radar. They expect - and rightly so - that medical product regulatory authorities are doing their jobs. However, as noted above, globalization has negatively impacted all patients, including me and your readers. While the benefits of globalization still exceed the costs, we can't tell that to the cancer patient that received counterfeit Avastin in the USA, or to the large numbers of pregnant women in Ghana who received ergometrine to induce labor for medically necessary reasons, yet when tested using statistically significant samples, there was little amount of active ingredient in either the injectable or tablet dosage forms, if detected at all.

5. You are working with a variety of leaders in healthcare related industries including pharmaceuticals. What would you say are the top three priority assets or skill sets needed for companies to be successful in the global healthcare industry?

Number one, remember that healthcare providers and patients are your consumers.
Number two, please never forget number one. Number three, please never forget number two.
Simple, right?

6. WKMJ has readers from over 10 countries globally. Please share your final words or thoughts with our readers.

I don't want to cause sensationalist concerns here. But manufacturers of medicines and devices are in the business of helping patients. If that is not your business's primary concern, then exit this industry. For those that focus on patients, the rewards - financial and otherwise - will be there. In conducting yourself accordingly, please understand that your patients no longer exist in your country alone. Your patients exist everywhere across the globe. There is someone, somewhere, buying your medicine and sending it somewhere else - often to places that you never even consider as part of your market. Those patients do not need to be victimized just because they aren't. Be diligent in your manufacturing and distribution practices, and know that if you do, you are really helping someone in dire need. And if you need support, Rx-360 is here and we can help.

Mark Paxton

Chief Executive Officer, Rx-360

Mark Paxton is the first CEO of RX-360, Prior to joining RX-360, he served as a Regulatory Counsel in the FDA CDER Office of Compliance where he was responsible for assisting in the development of supply chain security policies, both domestically and internationally. Before joining FDA, Mr. Paxton served as Associate Vice-President, International Regulatory Affairs at the Pharmaceutical Research and Manufacturers of America ("PhRMA"). In that capacity, he established a number of on-going dialogs and work programs with drug regulatory authorities throughout, Japan, China, East Asia, India, Europe and Latin America. Mr. Paxton is also a regulatory attorney by education, experience, and training, and prior to joining PhRMA, he was in private practice in Lexington, Kentucky where he focused his practice on food and drug law. He received his B.S. (1991) and M.S. (1993) degrees in Economics from the University of Kentucky, and his J.D. from the University of Dayton School of Law in 1998.

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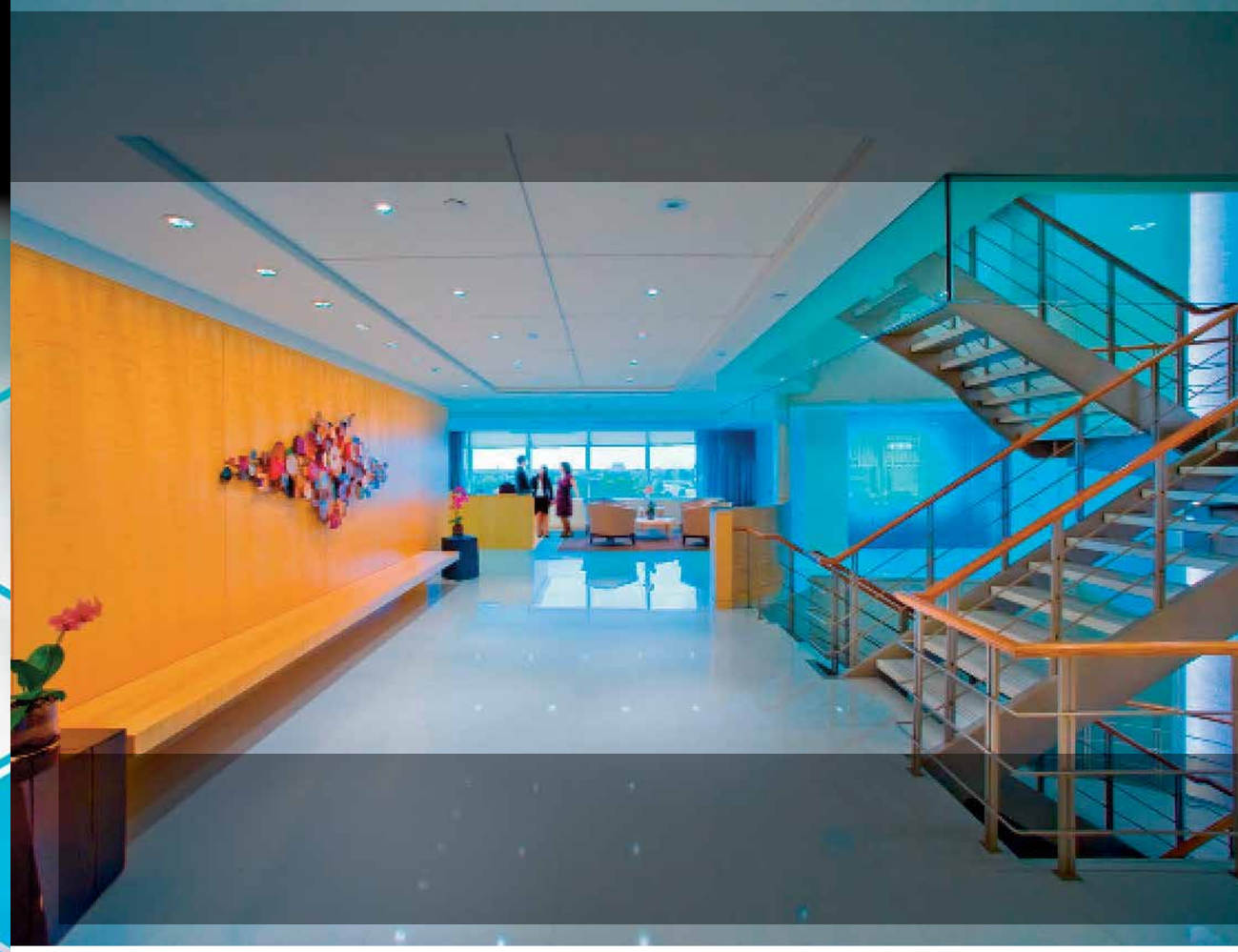

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Special Report

SPECIAL REPORT I

FEMALE URINARY INCONTINENCE &
KEGEL EXERCISE WITH BIOFEEDBACK

SPECIAL REPORT II

IN MEMORY OF DR.SAMMY LEE, WKMJ'S
VERY FIRST INSPIRATIONAL HEALTHCARE LEADER

SPECIAL REPORT I

Female Urinary Incontinence & Kegel Exercise with Biofeedback

Urinary incontinence is defined as an involuntary urine leakage under the definition of International Continence Society and is classified into stress-type, urgency-type, mixed-type, and overflow-type. Stress urinary incontinence (SUI) is involuntary urine leakage when abdominal pressure increases, such as cough, sneezing, and straining. Its major pathogenesis can be largely explained by two mechanisms; hypermobility of bladder neck and urethra when abdominal pressure increases due to postpartum weakening of pelvic muscle and pelvic atony in women; and deficiency of urethral sphincter itself.

Decline in quality of life and expenditure of medical bill due to urinary incontinence can give a great influence in women's social life. Prevalence of female urinary incontinence is 30~40% in younger women, increases in middle-aged women up to 30~50%, and stays at such level in older women. In regard to type of urinary incontinence, SUI is most common with 49%, second most common is mixed-type urinary incontinence with 29% and third most common is urgency-type urinary incontinence with 21%. As for prevalence in Korea, 24.4-41.2% complained of urinary incontinence when analyzing 1,000 or more women. Of those, SUI constituted 48.8%, mixed-type 41.6%, and urgency-type 7.7%, in which prevalence of SUI was the highest. Influence of urinary incontinence is not to be overlooked in socio-economical and individual aspects. Though there are not much data in Korea, based on data from western countries, more than 1.1 million patients in the U.S visited hospital for urinary incontinence as their chief complaints in year 2000 alone, and the amount spent in its diagnosis and treatment was 19.5 billion dollars, which is safe to say that it caused more socio-economical loss than any other chronic diseases. Analysis of individual patients revealed that women with severe urinary incontinence showed more severe depression, negative thoughts and lower satisfaction in quality of life, which induced various physical and psychological disorders.

SUI is majorly due to weakening of pelvic musculature and urethral sphincter and when some severe SUI symptoms arise to a certain level, surgical treatment is mostly conducted in Korea. But when symptom of the patient is not severe or patient refuses the surgery due to health status, there are some conservative treatments to improve symptoms. Conservative treatments of SUI include modification of life style, behavior therapy, and pelvic floor muscle exercise (PFME). Modification of life style is to alleviate symptoms of urinary incontinence by modifying chronic constipation, obesity, smoking, and caffeine intake, but its scientific evidence is weak to routinely approve such approach. Behavior therapy includes bladder training and education of voiding mechanism

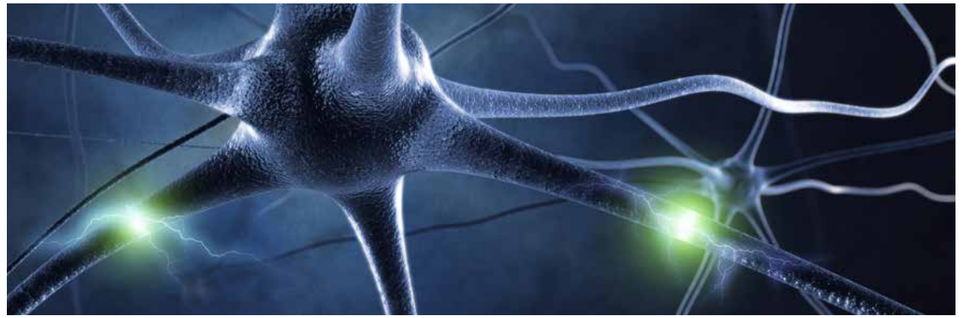
Previous studies found PFME with biofeedback to be more effective in improvement of pelvic floor muscle contraction than PFME alone

and is mostly effective in urgency-type urinary incontinence. Though it has been reported that it decreased around 50% of urinary incontinence in treatment of SUI, its effects in clinical practice is restrictive as the patient's motive in therapy is crucial.

PFME, among treatment of SUI, was first proposed by Dr. Arnold Kegel in 1948 for prevention and treatment of post-partum urinary incontinence and various modifications have been attempted to improve its therapeutic effect. Theological background of PFME is to increase muscular capacity with exercise and support pelvic organ structurally, preventing descent of bladder neck and urethra with quick pelvic floor muscle contraction when abdominal pressure abruptly increases. To be more specific, it is to enhance passive urinary continence by placing pelvic organ with reinforcing and hypertrophying pubo-coccygeous muscle among anal elevating muscles and active urinary continence of bladder neck and urethra with repetitive contraction exercise. In order for PFME to be effective, selection of appropriate patients is crucial. PFME has no side effect and does not affect other treatment so it can be utilized as primary treatment of SUI. However, it is more effective in patients with less severe symptoms, patients receiving estrogen therapy after menopause, patients with normal body weight, and patients with no history of previous urinary incontinence surgery. The most important point is that patient must recognize contraction and relaxation of pelvic muscle from education. To be said, muscles other than pelvic floor muscles like abdominal or buttock muscles should not contract and only pelvic floor muscles should be selectively contracted and relaxed for its maximum effect. There is no standard guideline on training frequency or repetition of PFME, but International Continence Society recommends 8 to 10 repetition with 6 to 8 seconds of contraction each time exercised 3 to 4 times a week. As for duration, it is recommended to be continued for at least 15 to 20 weeks. In recent meta-analysis, PFME showed cure rate of 56%, which showed improvement in cure rate of 8 times than control group and overall improvement rate of 17 times than the control group. Therefore, it can be effective as a primary treatment for SUI in optimal patient group.

Among PFME methods, 4 methods are commonly used in order to increase cognition of pelvic floor in patients and increase exercise outcome. Vaginal cone uses heavier vaginal cone stage by stage for patient to exercise while identifying pelvic floor muscle and has been approved of its effect from meta-analysis. In some cases, electrical stimulation and extracorporeal magnetic therapy can be conducted simultaneously with PFME, but the protocol has not yet been established and there are many negative opinions on its long-term effect.

Biofeedback includes all methods that give direct audiovisual stimuli to patient during exercise and modifying cognition and contraction of pelvic floor muscle. About 30% of patients were incapable of contracting pelvic floor muscles adequately when they heard PFME method via literature or verbal instruction, and biofeedback was introduced to supplement such problem and enhance its effect. In conclusion, it is to give feedback to patients by showing electromyography or sphincter pressure as audiovisual cues and train them repeatedly until they can selectively control the proper muscle. Though there is no standard guideline on biofeedback in PFME, continuous education is recommended after education of 30 minutes or longer, 2 or more times a week, for more than 1 month. In regard to simultaneous treatment of biofeedback in PFME, there are many conflicting reports on its significance in therapeutic effect, but it is recognized to be helpful in faster relief of urinary incontinence. Previous studies found PFME with biofeedback to be more effective in improvement of pelvic floor muscle contraction than PFME alone, whereas one study reported PFME with biofeedback to be more effective in improving pelvic floor muscle contraction, but with no additional benefit of average decrease in urinary incontinence. From analysis of 10 randomized studies, PFME with biofeedback was reported to be no more effective than PFME alone, but recent meta-analysis reported PFME with biofeedback to have some more advantage in improvement rate than PFME alone. In addition, one recent study reported that PFME with biofeedback alleviated SUI symptoms in earlier stage with use of new biofeedback device that uses vibration.



Such result of PFME treatment with biofeedback is facilitating many portable biofeedback PFME devices to be sold in market so that home training would be possible, rather than in hospital. Such portable devices use various biofeedback methods and increase outcome of PFME with improvement of probe mechanism. The most typical method would be to measure intra-vaginal pressure with intra-vaginal probe when the patient is conducting PFME and provide feedback after assessing whether patient is conducting PFME properly, which is clinically safe and shows great effect in relief and treatment of urinary incontinence. Such portable biofeedback devices are clinically safe and show great effect in relief and treatment of urinary incontinence. These devices also help achieve improvements in sexual function. W

Seong-Jin Jeong, M.D.

Professor of Urology, Seoul National University Bundang Hospital

Professor Jeong is an active clinician and surgeon in the field of voiding dysfunction and prostatic diseases, such as overactive bladder, incontinence, neurogenic bladder, and benign prostatic hyperplasia (BPH). He has conducted researches on various receptors in the urothelium and detrusor muscle, and plans to develop organ bath experiments. Professor Jeong is currently actively involved in the surgical treatment of male incontinence and in neuromodulation for overactive bladder. Also, he combines medical treatments for patients with various voiding dysfunctions.

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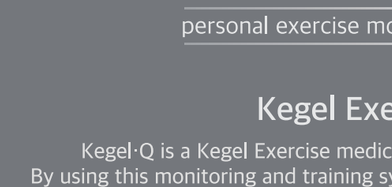

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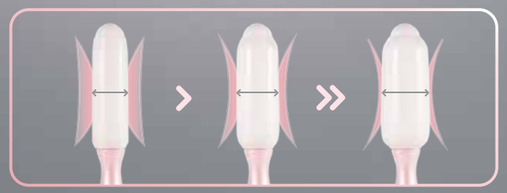

※ *Multicenter clinical trials are currently recruiting participants at reputable university hospitals in South Korea including Seoul National University Bundang Hospital and these trials are sponsored by Korea Health Industry Development Institute.*

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SPECIAL REPORT II

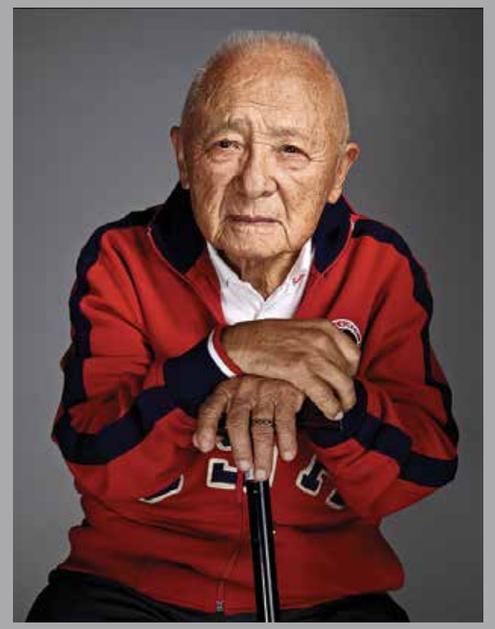
In Memory of Dr. Sammy Lee, WKMJ's Very First Inspirational Healthcare Leader

Dr. Samuel "Sammy" Lee, the Eminent Physician and the First Asian American Olympic Medalist

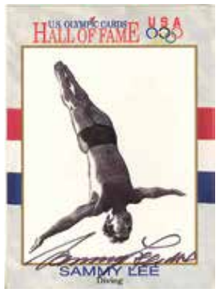
Samuel "Sammy" Lee, M.D. (August 1, 1920 – December 2, 2016) lived a full life with the achievements of a champion. He was a two time Olympic Gold Medalist in Platform Diving in back to back Olympics in London in 1948 and Helsinki in 1952. He was the first Asian American to win an Olympic gold medal for the United States. Born to Korean parents who dreamed of a better life away from the turmoil and Imperial Japanese colonization of the Korean Kingdom in the early 20th Century, Sammy grew up in California and became an inspirational figure of America.

My first encounter with Dr. Sammy Lee was during the Dedication of the Korean Studies Library at the University of Southern California. I was excited to hear him speak since we were both alumni of the USC Medical School. Sammy Lee graduated in an accelerated medical program in 1947 because of the acute need of physicians for the World War II effort on two fronts. Although he graduated after the VE and VJ Days 1945, he served as an active duty medical officer in the U.S. Army in South Korea from 1953 to 1955. Sammy was stationed in Seoul as a U.S. Army Ear, Nose, and Throat specialist and treated the first President of South Korea, Syngman Rhee.

Sammy encountered discrimination in many forms throughout his life. As a young diving trainee, he was only allowed to train at the Pasadena Brookside dive pool with other people of color, once a week on Wednesdays before the weekly pool draining and cleaning. He also encountered restrictive housing covenants and active petitions to bar him from owning a home in Orange County. Only through the help of friends like the young Richard Nixon, could he finally purchase a home there.



I had the fortune of meeting him again as one of the Keynote Speaker for the Korean American Medical Association Convention in Orange County in 2012. Sammy's eloquent speech inspired doctors of Korean descent from the United States, South Korea, and around the world. His inspirational speech helped us in the launch of the World Korean Medical Organizations at the meeting. He is the inspiration for all of our fellow physicians, as the most renowned doctor of Korean descent.

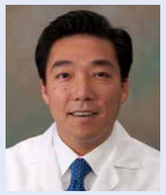


As an Olympic Champion, Sammy toured Asia on a friendly Goodwill Tour with the Department of State to enhance closer ties with peoples who needed the inspiration. Here he was, a non-Caucasian Olympian and doctor, representing the United States of America in diving demonstrations and speaking engagements. He even appeared on Groucho Marx's "You Bet Your Life" in 1956 with a partner from the Midwest and they both became the winners in the show.

Sammy was very active as a representative of the Pioneer generation for Korean American community life. He was sought after for many inspirational speeches and engagement throughout Los Angeles and around the world. . Dr. Sammy Lee Medical and Health Science Magnet Elementary School is a school in Los Angeles Koreatown that has been named after him in honor of his great accomplishments.

Sammy was the first profiled physician in the Inaugural World Korean Medical Journal issue. I am proud to have been present during the interview where he represented us as a Korean American physician of true heroic distinction. The fact that he was able to train for the Olympics while building his early medical career is something that will rarely, if ever, be repeated.

We are proud to call him our founding father in the group of physicians of Korean descent. He will serve as an inspiration not only to Korean communities around the world, but to anyone who belongs to a small struggling group of people whether they are exiles, refugees, or those otherwise seeking freedom from political, religious, or economic oppression. That he was able to succeed during a time in America when civil rights struggles were just beginning will serve as a beacon of hope for all who seek the dream of better lives. We honor his life and memory and his story will forever be remembered.



Jinha Park, MD, PhD

President, California Radiological Society

As an award-winning director of MRI and Radiology Research, he works to improve access to imaging screening tests and increase the role of diagnostic and interventional radiology in improving the diagnosis and treatment of patients.

Biopharmaceutical Report

BIOPHARMACEUTICAL REPORT I

POLITICIZING SCIENCE

BIOPHARMACEUTICAL REPORT II

HUMIRA BIOSIMILAR UNLIKELY TO REACH THE MARKET BEFORE 2020

BIOPHARMACEUTICAL REPORT III

ROCHE'S GALLIUM RESULTS DRAW SKEPTICISM ABOUT CHANGING PRACTICE IN FIRST-LINE FOLLICULAR LYMPHOMA

POLITICS, POLICY & LAW

POLITICIZING SCIENCE

BY STEVE USDIN, WASHINGTON EDITOR

While the FDA reform provisions in the 21st Century Cures Act give the agency backing to carefully advance some of its long-term objectives, an analysis of the bill's details suggests that when it comes to NIH, at best the legislation is a missed opportunity to make meaningful changes at the world's largest biomedical funding agency, leaving long-term problems untouched.

At worst, Cures will be a step backward that will politicize research and skew grant-making toward flashy, short-term translational science projects that are not designed to fill the knowledge gaps that prevent biopharma companies from developing scientific advances into new medicines.

Cures was propelled through Congress by passionate support for boosting NIH funding in the belief that more money will quickly lead to medical breakthroughs. In fact, the addition of $4.8 billion over a decade is unlikely to yield quick dividends.

Increased funding for NIH was the Democrats' price for supporting Cures legislation.

The version of the bill passed by the House of Representatives in 2015 would have created an $8.75 billion "Innovation Fund." The fund would have included a $2.5 billion Accelerating Advancement Program that the NIH director could invest in conjunction with institute directors based on their assessments of scientific opportunities.

The bill was revamped this summer, however, after Congress allocated the budget offsets that were the basis for mandatory funding to other priorities, fiscal hawks became queasy over the scale of the financial commitment, and Democrats came to fear that Cures was their last chance to boost NIH's budget ahead of an era of fiscal austerity.

The result was a bipartisan agreement to cut the NIH funding increase in half and eliminate provisions negotiated by House Energy & Commerce Committee Chair Fred Upton (R-Mich.) that would have made the funding mandatory.

"IT IS VERY IMPORTANT TO MAINTAIN AND INCREASE SUPPORT FOR UNDIFFERENTIATED RESEARCH."

ANONYMOUS NIH INSTITUTE DIRECTOR

Supporters of the act say it will create a binding commitment for Congress to appropriate the specified funding, but congressional appropriators could renege on the promises.

The Accelerating Advancement Program has been scrapped, and almost all the new money will be directed to three big translational science projects: the Precision Medicine ($1.5 billion), Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) ($1.5 billion) and Cancer Moonshot ($1.8 billion) initiatives.

This highly targeted funding will do little to change the low success rates of grant applications that define the lives of the vast majority of academic biomedical researchers.

In FY16, 19% of research project grants were funded, and NIH expects the success rate to fall to 17.5% this fiscal year.

Low success rates foster a climate of risk-aversion and cronyism at NIH as peer reviewers favor applications that are most likely to succeed and prefer those submitted by investigators with proven track records.

The average age of the first NIH R01 grant, the most common type of research grant, has been stuck at 42 for seven years. At the same time, the U.S.'s scientific workforce is graying. The number of NIH-funded researchers over 65 is double the number under 37.

A "capstone" program that was intended to ease aged researchers off the bench and into retirement was included in the original House-passed Cures bill but eliminated in the final version.

Cures will establish a Next Generation of Researchers Initiative, which consists of vague instructions to promote and prioritize policies that seek to increase opportunities for young researchers. There is no money or policy mandate attached to the initiative.

LESS CURIOUS

Earmarking funding for specific projects while inflation erodes the spending power of flat funding for the vast majority of science that falls outside those projects is not in the best interests of American science, according to two NIH institute directors who asked not to be named.

In recent years, even when total NIH funding has increased, new money has been earmarked for specific translational projects, they noted, so money available for curiosity-driven scientific research has been flat or has decreased.

"It is very important to maintain and increase support for undifferentiated research," one of the directors said. "[NIH Director Francis] Collins has pushed projects — BRAIN, Precision Medicine, Moonshot — and Congress and the president have gotten the false impression that this is the future of science."

Beyond these marquee projects, translational science has been "dominating, crowding out undifferentiated science that often is the basis for the most important breakthroughs," the director said.

Cures could have scaled back translational research spending to create room for more basic research, which is far less expensive. For example, it could have forced NIH to take a hard look at the many underpowered "pilot" clinical trials it funds, which benefit the careers of the academic investigators more than the patients who participate or the medical fields they are intended to advance.

Failing that, the new law could have — but won't — improve the efficiency of NIH's translational research by ensuring it produces robust, reproducible data that are highly relevant to the needs of biopharma companies that develop medicines.

The National Center for Advancing Translational Sciences (NCATS), which has formal policies intended to ensure that its research is partnered with product developers, will remain an outlier, physically and culturally separate from NIH's other institutes and centers.

Cures also will leave unchanged NIH's system for paying overhead costs, such as administrators, buildings and facilities, which can equal 50%. Reforming overhead payment policies, and requiring that universities pay a substantial portion of principal investigators' salaries, would have directed more NIH money to science.

While Congress and NIH could theoretically make these kinds of changes at any time, the tremendous hype surrounding the Cures bill has persuaded Capitol Hill that, when it comes to biomedical research, its job is done.

SETTING TERMS

21st Century Cures includes a section titled "Increasing Accountability at the National Institutes of Health" that will centralize power in the hands of the NIH director, make it easier for Congress to point the finger at institute directors if they approve controversial research, and inject political considerations into funding decisions.

The core provision will change the law to create renewable five-year terms for directors of each of NIH's 27 institutes and centers, except the National Cancer Institute. Like the NIH director, the NCI director will continue to be appointed by the president and subject to Senate confirmation.

The clock will start ticking on current institute and center directors the day President Obama signs the 21st Century Cures Act into law — scheduled for Tuesday. Whoever is the NIH director five years from that day will have the power to renew or dismiss these directors.

The law sets no limits on the number of times a director can be reappointed. Neither does it create any criteria or specify any procedures for the NIH director to apply when making renewal decisions.

> "INSTITUTE DIRECTORS WILL BE AFRAID TO CRITICIZE BAD IDEAS IF THEY COME FROM A PRESIDENTIALLY APPOINTED DIRECTOR WHO CAN FIRE THEM."
>
> ANONYMOUS NIH INSTITUTE DIRECTOR

"Institute directors will be afraid to criticize bad ideas if they come from a presidentially appointed director who can fire them," one of the institute directors told BioCentury. "There is no reason to believe that the president will always appoint great NIH directors. Some in the past have been impulsive and ideological."

Given the slow and unpredictable pace of science, and the fact that new directors will inherit multiyear programs, it will be very difficult for institute directors to produce obvious results in a five-year period. This could create incentives for directors to pursue short-term wins, and to bow to or anticipate the ideological principles and intellectual preferences of the NIH director.

In addition, decisions about renewing an institute director's tenure will often be made by an NIH director who may not have appointed her.

All of these considerations could diminish the stature of NIH institute directors from one of the most prestigious positions in science to way stations for mid-level managers from research universities to burnish their resumes, according to the leader of a scientific society who did not wish to be named.

POINTING FINGERS

Cures also will facilitate a game of finger-pointing that has been popular in Congress for generations. The game starts with staffers combing through thousands of grants until they find one with a funny or unusual name, and then calling it out as a symptom of waste.

Because Cures requires that institute directors personally "review and make the final decision" on all research grants, congressional committees now will be able to haul institute directors to public hearings to justify any grant. This isn't likely to engender risk-taking.

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This provision, like the governance provisions, was proposed by Rep. Andy Harris (R-Md.).

In addition to dramatically expanding the NIH director's power, Harris has publicly announced his strong interest in exercising that power by becoming the next NIH director. So far, the Trump transition team hasn't divulged its plans for NIH.

Harris, who was an obstetric anesthesiologist for three decades and an investigator on one NIH grant prior to his election to Congress, would be a radical departure from tradition. If nominated and confirmed, he would be the first NIH director since NIH's predecessor agencies were created in 1887 who lacked extensive experience as a scientific researcher or leader of research teams. A member of the Freedom Caucus, he opposes embryonic stem cell research.

Collins has met with and charmed hundreds of members of Congress, creating immense goodwill for NIH among politicians who aren't noted for their enthusiasm for science or spending. He spent enormous amounts of time with the architects of Cures, and the legislation was written with the idea that someone very much like Collins would be running NIH.

The chairs of four congressional committees and subcommittees with oversight authority over NIH, including Upton, have written to Trump urging him to retain Collins.

COMPANIES AND INSTITUTIONS MENTIONED

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U.S. Food and Drug Administration (FDA), Silver Spring, Md.

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BIOPHARMACEUTICAL REPORT II

Humira Biosimilar Unlikely to Reach the Market Before 2020

The numerous biosimilars for AbbVie's (NYSE:ABBV) Humira (adalimumab) are unlikely to reach the market prior to Amgen's (NASDAQ:AMGN) approved biosimilar, Amjevita, and certainly not before 2020, legal experts agreed. AbbVie's patent estate for Humira is far too complex and Amgen has enough of a head start advantage with its approval and ongoing litigation that is not likely another biosimilar could surpass it to market, they said. Further, legal experts agreed it is more likely a Humira biosimilar would reach the market in 2022.

Analysts have said despite Amgen's biosimiliar being the first to receive approval, Coherus Biosciences' (NASDAQ:CHRS) biosimilar, CHS-1420, could be the first to hit the market and as soon as 2018 based on its formulation are dosing infringing less on AbbVie's patent estate than other challengers.

However, legal experts this news service spoke to said, Coherus and other manufacturers will have to face the same legal battle as Amgen and even a formulation advantage would not be sufficient for an earlier launch.

On 23 September, the FDA approved Amjevita as the first Humira biosimilar for the same indications as the originator. Humira was approved by the FDA in 2002.

Coherus announced positive top-line Phase III results with CHS-1420 on 8 August, following results from four prior successful Phase IIIs. The company said it plans to file a BLA in 2H16 and launch in 2018, according to the 8 August press release.

After Coherus failed to bring an IPR challenge against Amgen in November, analysts said they viewed this as only a minor setback for the company, and that it still has potential to be the first to launch as early as 2018.

A spokesperson for Amgen said the company does not comment on other companies' products, but the firm intends to comply with its obligations under the BPCIA and does not anticipate launching in 2017. Amgen is evaluating various launch scenarios at this time, she noted. Coherus and AbbVie did not respond to requests for comment

Amgen's head start unchallenged

AbbVie is going to sue every subsequent challenger in the same way it sued Amgen, said Michael Fuller, partner, Knobbe Martens, San Diego, California. The companies have already engaged in the patent dance put forth by the Biologics Price Competition and Innovation Act (BPCIA), and AbbVie has sued Amgen on 10 patents to date. Amjevita has received approval, but as soon as Amgen gives its 180 days notice to launch, AbbVie will sue on the 51 patents it has not yet sued on, Fuller said. Any manufacturer coming after Amgen will have to run the same gauntlet, agreed Christopher Betti, partner, Morgan Lewis, Chicago, Illinois and a third IP lawyer.

While invalidating patents would knock them out for subsequent challengers, potentially making the road smoother, it is more likely that Amgen will show instead how it does not infringe on many of these patents, which means they will remain in place for other companies, Fuller explained. Further, even if Amgen does invalidate patents for subsequent challenger, it will still have start to market from having gone through the whole litigation process, he said.

The litigation process is so complicated there is no way another manufacturer, including Coherus, can avoid going through the same legal hurdles, agreed the third lawyer. However, she said it is too difficult to speculate at this point whether Amjevita will indeed be the first Humira biosimilar to launch.

Other Humira biosimilar manufacturers including Coherus have made different formulations and tried to weave their way through AbbVie's portfolio, but it is complex and well-crafted, said Betti. Even if Coherus has an alleged formulation advantage, he noted, there are manufacturing and use type patents that will prove more problematic. There are 61 patents, only a few of which have anything to do with the formulation, said fuller. Betti and Fuller agreed the manufacturing and use type patents may be the most difficult for any company to challenge.

AbbVie's patents '157, '158 and '166 are among those that deal with Humira's formulation. The US Patent and Trademark Office's (PTO) Patent Trial and Appeal Board (PTAB) announced in November that it would not embark on an inter partes review (IPR) of AbbVie's '166 formulation patent that Coherus requested. However, in May the PTAB agreed to embark on an IPR or AbbVie's '135 methods patent, which analysts saw as a win for Coherus. The '135 patent covers the method of treating rheumatoid arthritis (RA) by administering Humira subcutaneously according to a particular dosing schedule.

As soon as Coherus gets its BLA approved by the FDA, it will be in the exact same place as Amgen is now, that being in a lawsuit of up to 10 patents initially, followed by assertion of about 50 patents as soon as Coherus announces their intent to launch in 180 days, Fuller said.

Many biosimilar companies have launched IPR, but these are piecemeal and only small hits ay a very large portfolio, Betti said. While the IPR strategy has the advantage of being less risky, doable without FDA approval and allows companies to test the waters, the downside is that the same arguments cannot be used subsequently in district court if the IPR fails, he explained.

Amgen is a bigger company with more resources that many of the other biosimilar manufacturers and it can afford to battle this out, agreed Fuller, Betti and the third lawyer. Hence, a lot of other companies are sitting back and waiting for Amgen to pave the way, they added.

Timeframe

No Humira biosimilar will be on the market as soon as 2018, said Fuller. Amgen and AbbVie have litigation set for November 2019 and that will likely result in appeals, which will take them into 2020, he said. AbbVie has said its patent is good until 2022 and it will work hard to keep others off the market until then, he added.

Amjevita is likely to be the first to market, but the litigation is going to take at least an additional two to five years, said Betti, adding that Amgen is unlikely to pursue an at-risk launch and launch based on FDA approval, because the stakes would be too high for the company. It is unlikely any Humira biosimilar will be launched until 2022, agreed the third lawyer. W

Alissa Fleck

Journalist, New York

Alissa is a former freelance editor and journalist who has been a regular contributor for Bankrate, the Huffington Post, Truthout, Global Post and three Straus News publications in Manhattan. She has written medical and health copy for websites including SF Gate (the San Francisco Chronicle online) and Livestrong as well as for private clients.

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Small blood sample for glucose monitoring

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- Weight: 14.29g

Features

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Rayburn House Office Building
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June, 2016

Keynote Speaker:
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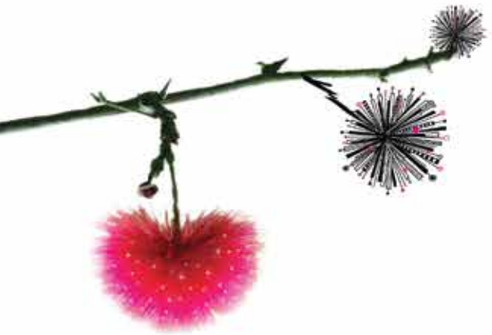
Congressman Charles Rangel



Happy smile and hope after pain

Cancer-free D.K. Lee

D.K. Lee has related to It's A Wig that she will promote to cancer patients about the beauty classes and healing programs she attended. The beauty classes are held at Kyung Hee Medical Center and it is for cancer patients to help them feel more womanly during their hard times. She would like to thank all the people who gave her hope. "Thank you for giving me a second chance to live as a woman. With the hopes and gifts that I have received, it encourages me to work harder to volunteer my time for the people who are fighting against cancer."

Kyung Hee Medical Center patient
D. K. Lee

D.K. Lee attending
beauty classes while chemotherapy treatment

BIOPHARMACEUTICAL REPORT III

Roche's GALLIUM Results Draw Skepticism about Changing Practice in First-Line Follicular Lymphoma

Roche's (VTX:ROG) Phase III GALLIUM study of Gazyva (obinutuzumab) in first-line follicular lymphoma (FL) has low probability of changing practice in the near term despite showing an improvement in progression-free survival (PFS), most experts said.

Speaking on the sidelines of the recently concluded American Society of Hematology (ASH) meeting in San Diego, California, experts pointed to the lack so far of overall survival (OS) data as well as economic and logistical factors that would limit Gazyva's ability to replace Roche's Rituxan (rituximab) in clinical practice.

Roche shares rose 1.7% on news of the GALLIUM results, which were shown in an oral presentation at ASH on 5 December and announced in a company press release.

Gazyva's sales in non-Hodgkin's lymphomas (NHL) are expected to rise from USD 36m at YE16 to more than USD 1.3bn by YE20, while Rituxan's sales are expected to fall from USD 306m to USD 73m during the same timeframe. Rituxan is approved for NHL, chronic lymphocytic leukemia (CLL) and rheumatoid arthritis, while Gazyva is approved for relapsed/refractory FL and CLL. FL is the most common indolent NHL subtype.

GALLIUM data will be submitted to regulators for an expansion of Gazyva's label, Roche said in the 5 December press release. The company did not respond to a request for comment.

Skepticism around practice-change potential

While an OS benefit in FL would be "absolutely compelling," said Dr Joshua Brody, assistant professor, Medicine, Mount Sinai Hospital, New York, nevertheless the question of whether GALLIUM's PFS benefit would prompt doctors to switch from Rituxan to Gazyva was a difficult one. A comparable case, he noted, is the Phase III PRIMA study (NCT00140582), which evaluated Rituxan maintenance therapy following Rituxan/chemotherapy induction versus no maintenance therapy. Though PRIMA showed a PFS benefit for Rituxan maintenance, it did not show an OS benefit and thus did not change practice, he explained, and the same could be true for the GALLIUM PFS results.

GALLIUM showed a 34% increase in PFS for the Gazyva arm versus the Rituxan arm, though the PFS median was not reached, according to the aforementioned press release. Three-year PFS rates were respectively 81.9% and 77.9% by independent review, while three-year OS rates were 94% and 92.1%. The study included 1,202 FL patients randomized 1:1. Both arms also received chemotherapy options- including cyclophosphamide/doxorubicin/vincristine/prednisone (CHOP), cyclophosphamide/vincristine/prednisone (CVP) or Teva Pharmaceutical Industries' (NYSE:TEVA) Treanda (bendamustine). Of GALLIUM's total 1,401 patients, the remainder had marginal zone lymphoma, another indolent NHL histology, but they were not included in the ASH analysis.

The GALLIUM data and Gazyva's OS benefit in CLL points to the potential for an eventual OS benefit in first-line FL, said Brody. A benefit in OS- one of the study's secondary endpoints- is difficult and time-consuming to show given the indolent nature of FL and the many therapies patients receive in their lifetimes, noted Dr Paul Hamlin, chief, Medical Oncology Service, Memorial Sloan Kettering Cancer Center, Basking Ridge, New Jersey, and Dr Deepa Jagadeesh, associate staff, Department of Hematologic Oncology and Blood Disorders, Cleveland Clinic, Ohio.

Meanwhile, Dr Loretta Nastoupil, assistant professor, Department of Lymphoma/Myeloma, The University of Texas MD Anderson Cancer Center, Houston, said the GALLIUM data could shift frontline FL treatment in favor of Gazyva because it showed superiority for the newer drug.

However, Jagadeesh and Hamlin noted, another factor that may hold Gazyva back is economics, as the availability of subcutaneous and biosimilar Rituxan may continue to drive preference for the older drug. Brody agreed, adding SubQ and biosimilar Rituxan are likely to see quick uptake once they become available in the US, Brody said. Cost becomes an issue, especially in the context of great discussion thereof, Jagadeesh said, adding she plans to stick with Rituxan in her practice.

The FDA has accepted the BLA for SubQ Rituxan in blood cancers, according to a 3 November press release by Halozyme (NASDAQ:HALO), whose recombinant human hyaluronidase technology was used to develop the formulation. The EMA approved the SubQ formulation for FL in March 2014; Roche markets Rituxan as MabThera in Europe, and Gazyva as Gazyvaro. Rituxan's US patent expired in September, while it lost patent protection in Europe in 2013. EMA approval and launch of a biosimilar MabThera from Novartis (VTX:NOVN) generics unit Sandoz is expected in 2Q17, according to an analyst report.

Another factor potentially favoring Rituxan over Gazyva is the latter's higher incidence of infusion reactions, Brody said. Infusion reactions can be quite disruptive in smaller community oncology practices, which may also affect decisions of

whether to switch from Rituxan to Gazyva, he noted. Given the manageability of infusion reactions, Jagadeesh noted the impact of infusion reactions on prescribing habits is less clear.

Grade 3 or higher infusion-related reactions occurred among 12.4% of Gazyva-treated patients in GALLIUM versus 6.7% of those treated with Rituxan, according to the Roche release. The overall rate of Grade 3 or higher adverse events were respectively 74.6% and 67.8%.

The potential still exists for GALLIUM to change practice, Hamlin said, based on his view that Gazyva has a better MOA than Rituxan given improved PFS. Gazyva's higher dosage compared to Rituxan does not explain the former's benefit, he added. Gazyva recognizes a different CD20 epitope from Rituxan and is designed to have better binding between its Fc region and the Fc-gamma-R3a expressed by effector cells and improved antibody-dependent cellular cytotoxicity (Gagez, Cartron. Curr Opin Oncol. 2014 Sep;26(5):484-91).

Patients in GALLIUM's Gazyva arm received a flat 1,000mg dose on days 1, 8 and 15 of cycle 1 and on day 1 of seven 21-day or five 28-day cycles. On the other hand, those in the Rituxan arm received 375/m2 on day one of eight 21-day cycles or six 28-day cycles, followed by 375mg/m2 every two months for up to two years until progression.

Alaric DeArment
Reporter, New York

Alaric DeArment covers cancer drug development for BioPharm Insight. He served as associate editor of Drug Store News from 2008 to 2014, covering branded and generic drugs from development to distribution, retail and specialty pharmacy and regulatory affairs. In 2011-2012, he edited the book Contestation and Adaption: The Politics of National Identity in China. A native of Seattle, he graduated with honors with a bachelor degree in journalism from Ball State University and also lived in China from 2001-2004. Follow Alaric on Twitter @AlaricD_BPI

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#1 **Prescribed oral antiviral** according to US prescription data for treatment of CHB[1a]

COMPLETE RESPONSE RESULTS AT YEAR 1...

AT YEAR 1
The primary endpoint—complete response*—was evaluated in Studies 102 and 103[2]

THROUGH YEAR 8
Resistance was evaluated as a secondary endpoint[2,3]

In Study 102 (HBeAg–, n=375) and Study 103 (HBeAg+, n=266), a combined total of 641 adult patients with chronic hepatitis B (CHB) and compensated liver disease who were primarily nucleoside treatment naïve entered a 48-week, randomized, double-blind, active-controlled treatment period comparing VIREAD 300 mg to adefovir dipivoxil 10 mg. Subjects who completed double-blind treatment at Week 48 were eligible to roll over with no interruption in treatment to open-label VIREAD. Of 641 patients enrolled in the initial trials, 412 (64%) completed 384 weeks of treatment.[2]

***The primary endpoint in Studies 102 and 103 was complete response to treatment at 48 weeks as defined by HBV DNA <400 copies/mL (69 IU/mL) + histological response (Knodell necroinflammatory score improvement of ≥2 points without worsening in Knodell fibrosis score). Annual evaluation of resistance was a prespecified secondary endpoint. Cumulative VIREAD genotypic resistance was evaluated annually for up to 384 weeks in Studies 102, 103, 106, 108, and 121.[2,3]**

71% of HBeAg– VIREAD patients vs **49%** of adefovir dipivoxil patients.[2-4]
67% of HBeAg+ VIREAD patients vs **12%** of adefovir dipivoxil patients.[2,3,5]

INDICATION AND USAGE

VIREAD® (tenofovir disoproxil fumarate) is indicated for the treatment of chronic hepatitis B in adults and pediatric patients 12 years of age and older.

The following points should be considered when initiating therapy with VIREAD for the treatment of HBV infection:

- The indication in adults is based on data from treatment of subjects who were nucleoside–treatment-naïve and treatment-experienced with documented resistance to lamivudine. Subjects were adults with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease
- VIREAD was evaluated in a limited number of subjects with chronic hepatitis B and decompensated liver disease
- The numbers of subjects in clinical trials who had adefovir resistance-associated substitutions at baseline were too small to reach conclusions of efficacy

IMPORTANT SAFETY INFORMATION

BOXED WARNING: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT EXACERBATION OF HEPATITIS

- **Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals**
- **Severe acute exacerbations of hepatitis have been reported in HBV-infected patients who have discontinued anti-hepatitis B therapy, including VIREAD. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including VIREAD. If appropriate, resumption of anti-hepatitis B therapy may be warranted**

[a]Healthcare Analytics Monthly data, August 2014-June 2015.

Please see Brief Summary of full Prescribing Information including **BOXED WARNING** on the following pages.

GILEAD IS COMMITTED TO THE EDUCATION AND TREATMENT OF CHRONIC HEPATITIS B.

Viread® 300mg tablets
tenofovir disoproxil fumarate

Not an actual patient, but is representative of a real patient type. Models are used for illustrative purposes only.

...AT 8 YEARS: NO RESISTANCE WAS

Annual evaluation of resistance was a prespecified secondary endpoint for Studies 102 and 103 in HBeAg- and HBeAg+ chronic hepatitis B patients[3]; no evidence of resistance was found. Cumulative VIREAD genotypic resistance was evaluated annually for up to 384 weeks in Studies 102, 103, 106, 108, and 121.[2,4,5]

- In the nucleotide-naïve population from Studies 102 and 103, HBeAg+ subjects had a higher baseline viral load than HBeAg– subjects and a significantly higher proportion of the subjects remained viremic at their last time point on VIREAD monotherapy (15% vs 5%, respectively)[2]
- HBV isolates from these subjects who remained viremic showed treatment-emergent substitutions; however, no specific substitutions occurred at a sufficient frequency to be associated with resistance to VIREAD (genotypic and phenotypic analyses)[2]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

- **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of VIREAD. In all patients, assess estimated creatinine clearance (CrCl) prior to initiating and during therapy. In patients at risk for renal dysfunction, including those who previously experienced renal events while receiving adefovir dipivoxil, additionally monitor serum phosphorus, urine glucose, and urine protein. In patients with CrCl <50 mL/min, adjust dosing interval and closely monitor renal function. Avoid concurrent or recent use with a nephrotoxic agent. Cases of acute renal failure, some requiring hospitalization and renal replacement therapy, have been reported after initiation of high dose or multiple NSAIDs in HIV-infected patients with risk factors for renal dysfunction; consider alternatives to NSAIDs in these patients. Persistent or worsening bone pain, pain in extremities, fractures and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function
- **Coadministration with other products:**
  – Do not use in combination with other products containing tenofovir disoproxil fumarate
  – Do not administer in combination with adefovir dipivoxil
- **Patients coinfected with HIV-1 and HBV:** Due to the risk of development of HIV-1 resistance, VIREAD should only be used in HIV-1 and HBV coinfected patients as part of an appropriate antiretroviral combination regimen. HIV-1 antibody testing should be offered to all HBV-infected patients before initiating therapy with VIREAD
- **Bone effects:** Decreases in bone mineral density (BMD) and mineralization defects, including osteomalacia, have been seen in patients treated with VIREAD. Consider assessment of BMD in adult and pediatric patients who have a history of pathologic bone fracture or other risk factors for bone loss. In a clinical trial conducted in pediatric subjects 12 to <18 years of age with chronic hepatitis B, total body BMD gain was less in VIREAD-treated subjects as compared to the control group. In patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms, hypophosphatemia and osteomalacia secondary to proximal renal tubulopathy should be considered

ADVERSE REACTIONS

- **In HBV-infected subjects with compensated liver disease:** Most common adverse reaction (all grades) was nausea (9%). Other treatment-emergent adverse reactions reported in >5% of patients treated with VIREAD included: abdominal pain, diarrhea, headache, dizziness, fatigue, nasopharyngitis, back pain, and skin rash
- **In HBV-infected subjects with decompensated liver disease:** Most common adverse reactions (all grades) reported in ≥10% of patients treated with VIREAD were abdominal pain (22%), nausea (20%), insomnia (18%), pruritus (16%), vomiting (13%), dizziness (13%), and pyrexia (11%)

DRUG INTERACTIONS

- **Didanosine:** Coadministration increases didanosine concentrations. Use with caution and monitor for evidence of didanosine toxicity (e.g., pancreatitis, neuropathy). Didanosine should be discontinued in patients who develop didanosine-associated adverse reactions. In patients weighing >60 kg, the didanosine dose should be reduced to 250 mg once daily when it is coadministered with VIREAD and in patients weighing <60kg, the didanosine dose should be reduced to 200 mg once daily when coadministered with VIREAD

DETECTED AT YEAR 1 THROUGH YEAR 8

NO HBV RESISTANCE DEVELOPED YEAR 1 through YEAR 8

in clinical trials (Studies 102 and 103)[2,3]*

*Data for Years 2 through 8 are from the open-label phase.[6]

- There was a 64% (412/641) retention rate at Year 8: 266/426 patients given VIREAD→VIREAD; 146/215 patients given adefovir dipivoxil→VIREAD[2,6]

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS (cont'd)

- **HIV-1 protease inhibitors:** Coadministration decreases atazanavir concentrations and increases tenofovir concentrations; use atazanavir given with ritonavir. Coadministration of VIREAD with atazanavir and ritonavir, darunavir and ritonavir, or lopinavir/ritonavir increases tenofovir concentrations. Monitor for evidence of tenofovir toxicity
- **Drugs affecting renal function:** Coadministration of VIREAD with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir

DOSAGE AND ADMINISTRATION

- Recommended dose, in adults and pediatric patients ≥12 years of age (≥35 kg), for the treatment of chronic hepatitis B: one 300 mg tablet, once daily, taken orally, without regard to food
- In the treatment of chronic hepatitis B, the optimal duration of treatment is unknown
- Safety and efficacy in pediatric patients <12 years of age or weighing <35kg with chronic hepatitis B have not been established
- The dosing interval of VIREAD should be adjusted (using recommendations in the table below) and renal function closely monitored in patients with baseline creatinine clearance <50 mL/min

DOSAGE ADJUSTMENT FOR PATIENTS WITH ALTERED CREATININE CLEARANCE

	Creatinine clearance (mL/min)[a]			Hemodialysis patients
	≥50	30-49	10-29	
Recommended 300 mg dosing interval	Every 24 hours	Every 48 hours	Every 72 to 96 hours	Every 7 days or after a total of approximately 12 hours of dialysis[b]

[a]Calculated using ideal (lean) body weight.

[b]Generally once weekly assuming three hemodialysis sessions a week of approximately 4 hours duration. VIREAD should be administered following completion of dialysis.

- The pharmacokinetics of tenofovir have not been evaluated in non-hemodialysis patients with creatinine clearance <10 mL/min; therefore, no dosing recommendation is available for these patients
- No dose adjustment is necessary for patients with mild renal impairment (creatinine clearance 50-80 mL/min). Routine monitoring of estimated creatinine clearance, serum phosphorus, urine glucose, and urine protein should be performed in these patients
- No data are available to make dose recommendations in pediatric patients with renal impairment

Please see Brief Summary of full Prescribing Information including **BOXED WARNING** on the following pages.

References: 1. Data on file, Gilead Sciences, Inc. Healthcare Analytics. **2.** VIREAD [package insert]. Foster City, CA: Gilead Sciences, Inc.; May 2015. **3.** Marcellin P, Heathcote EJ, Buti M, et al. Tenofovir disoproxil fumarate versus adefovir dipivoxil for chronic hepatitis B. *N Engl J Med.* 2008;359(23):2442-2455. **4.** Data on file, Gilead Sciences, Inc. Study 102 CSR. **5.** Data on file, Gilead Sciences, Inc. Study 103 CSR. **6.** Marcellin P, Gane EJ, Flisiak R, et al. Long term treatment with tenofovir disoproxil fumarate for chronic hepatitis B infection is safe and well tolerated and associated with durable virologic response with no detectable resistance: 8 year results from two phase 3 trials [AASLD abstract 229]. *Hepatology.* 2014;60(4)(suppl):313A-314A.

For more information, visit www.viread.com/hcp

300 mg tablets
Viread®
tenofovir disoproxil fumarate

VIREAD® (tenofovir disoproxil fumarate) tablets

Brief summary of full Prescribing Information. Please see full Prescribing Information including Boxed WARNING. Rx only

WARNING: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT EXACERBATION OF HEPATITIS

- **Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals *(See Warnings and Precautions)***
- **Severe acute exacerbations of hepatitis have been reported in HBV-infected patients who have discontinued anti-hepatitis therapy, including VIREAD. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including VIREAD. If appropriate, resumption of anti-hepatitis B therapy may be warranted *(See Warnings and Precautions)***

INDICATIONS AND USAGE: VIREAD is indicated for the treatment of chronic hepatitis B in adults and pediatric patients 12 years of age and older.

The following points should be considered when initiating therapy with VIREAD for the treatment of HBV infection:

- The indication in adults is based on safety and efficacy data from treatment of subjects who were nucleoside-treatment-naïve and subjects who were treatment-experienced with documented resistance to lamivudine. Subjects were adults with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease *(See Adverse Reactions)*
- VIREAD was evaluated in a limited number of subjects with chronic hepatitis B and decompensated liver disease *(See Adverse Reactions)*
- The numbers of subjects in clinical trials who had adefovir resistance-associated substitutions at baseline were too small to reach conclusions of efficacy

DOSAGE AND ADMINISTRATION: For the treatment of chronic hepatitis B the recommended dose, in adults and pediatric patients ≥12 years of age (≥35 kg), is one 300 mg tablet, once daily, taken orally, without regard to food. In the treatment of chronic hepatitis B, the optimal duration of treatment is unknown. Safety and efficacy in pediatric patients <12 years of age with chronic hepatitis B weighing <35 kg have not been established. **Dose Adjustment for Renal Impairment in Adults:** Significantly increased drug exposures occurred when VIREAD was administered to subjects with moderate to severe renal impairment. Therefore, the dosing interval of VIREAD tablets 300 mg should be adjusted in patients with baseline creatinine clearance <50 mL/min using the recommendations in Table 1. These dosing interval recommendations are based on modeling of single-dose pharmacokinetic data in non-HIV and non-HBV infected subjects with varying degrees of renal impairment, including end-stage renal disease (ESRD) requiring hemodialysis. The safety and effectiveness of these dosing interval adjustment recommendations have not been clinically evaluated in patients with moderate or severe renal impairment, therefore clinical response to treatment and renal function should be closely monitored in these patients *(See Warnings and Precautions)*. No dose adjustment of VIREAD tablets 300 mg is necessary for patients with mild renal impairment (creatinine clearance 50–80 mL/min). Routine monitoring of calculated creatinine clearance, serum phosphorus, urine glucose and urine protein should be performed in patients with mild renal impairment *(See Warnings and Precautions)*.

Dosage Adjustment for Adult Patients with Altered Creatinine Clearance

	Creatinine clearance (mL/min)[a]			Hemodialysis patients
	≥50	30-49	10-29	
Recommended 300 mg dosing interval	Every 24 hours	Every 48 hours	Every 72 to 96 hours	Every 7 days or after a total of approximately 12 hours of dialysis[b]

a. Calculated using ideal (lean) body weight.

b. Generally once weekly assuming three hemodialysis sessions a week of approximately 4 hours duration. VIREAD should be administered following completion of dialysis.

The pharmacokinetics of tenofovir have not been evaluated in non-hemodialysis patients with creatinine clearance <10 mL/min; therefore, no dosing recommendation is available for these patients. No data are available to make dose recommendations in pediatric patients with renal impairment.

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS: Lactic Acidosis/Severe Hepatomegaly with Steatosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals. A majority of these cases have been in women. Obesity and prolonged nucleoside exposure may be risk factors. Particular caution should be exercised when administering nucleoside analogs to any patient with known risk factors for liver disease; however, cases have also been reported in patients with no known risk factors. Treatment with VIREAD should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations). **Exacerbation of Hepatitis after Discontinuation of Treatment:** Discontinuation of anti-HBV therapy, including VIREAD, may be associated with severe acute exacerbations of hepatitis. Patients infected with HBV who discontinue VIREAD should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. If appropriate, resumption of anti-hepatitis B therapy may be warranted. **New Onset or Worsening Renal Impairment:** Tenofovir is principally eliminated by the kidney. Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported with the use of VIREAD *(See Adverse Reactions)*. It is recommended that estimated creatinine clearance be assessed in all patients prior to initiating therapy and as clinically appropriate during therapy with VIREAD. In patients at risk of renal dysfunction, including patients who have previously experienced renal events while receiving adefovir dipivoxil, it is recommended that estimated creatinine clearance, serum phosphorus, urine glucose, and urine protein be assessed prior to initiation of VIREAD, and periodically during VIREAD therapy. Dosing interval adjustment of VIREAD and close monitoring of renal function are recommended in all patients with creatinine clearance <50 mL/min *(See Dosage and Administration)*. No safety or efficacy data are available in patients with renal impairment who received VIREAD using these dosing guidelines, so the potential benefit of VIREAD therapy should be assessed against the potential risk of renal toxicity. VIREAD should be avoided with concurrent or recent use of a nephrotoxic agent (e.g., high-dose or multiple non-steroidal anti-inflammatory drugs (NSAIDs)) *(See Drug Interactions)*. Cases of acute renal failure after initiation of high dose or multiple NSAIDs have been reported in HIV-infected patients with risk factors for renal dysfunction who appeared stable on tenofovir DF. Some patients required hospitalization and renal replacement therapy. Alternatives to NSAIDs should be considered, if needed, in patients at risk for renal dysfunction. Persistent or worsening bone pain, pain in extremities, fractures and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function in at-risk patients. **Coadministration with Other Products:** VIREAD should not be used in combination with the fixed-dose combination products ATRIPLA®, COMPLERA®, STRIBILD® or TRUVADA® since tenofovir disoproxil fumarate is a component of these products. VIREAD should not be administered in combination with adefovir dipivoxil *(See Drug Interactions)*. **Patients Coinfected with HIV-1 and HBV:** Due to the risk of development of HIV-1 resistance, VIREAD should only be used in HIV-1 and HBV coinfected patients as part of an appropriate antiretroviral combination regimen. HIV-1 antibody testing should be offered to all HBV-infected patients before initiating therapy with VIREAD. It is also recommended that all patients with HIV-1 be tested for the presence of chronic hepatitis B before initiating treatment with VIREAD.

Bone Effects

Bone Mineral Density: In clinical trials in HIV-1 infected adults, VIREAD was associated with slightly greater decreases in bone mineral density (BMD) and increases in biochemical markers of bone metabolism, suggesting increased bone turnover relative to comparators. Serum parathyroid hormone levels and 1,25 Vitamin D levels were also higher in subjects receiving VIREAD *(See Adverse Reactions)*.

Clinical trials evaluating VIREAD in pediatric and adolescent subjects were conducted. Under normal circumstances, BMD increases rapidly in pediatric patients. In HIV-1 infected subjects aged 2 years to less than 18 years, bone effects were similar to those observed in adult subjects and suggest increased bone turnover. Total body BMD gain was less in the VIREAD-treated HIV-1 infected pediatric subjects as compared to the control groups. Similar trends were observed in chronic hepatitis B infected adolescent subjects aged 12 years to less than 18 years. In all pediatric trials, skeletal growth (height) appeared to be unaffected *(See Adverse Reactions)*.

The effects of VIREAD-associated changes in BMD and biochemical markers on long-term bone health and future fracture risk are unknown. Assessment of BMD should be considered for adults and pediatric patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. Although the effect of supplementation with calcium and vitamin D was not studied, such supplementation may be beneficial for all patients. If bone abnormalities are suspected then appropriate consultation should be obtained.

Mineralization Defects: Cases of osteomalacia associated with proximal renal tubulopathy, manifested as bone pain or pain in extremities and which may contribute to fractures, have been reported in association with the use of VIREAD *(See Adverse Reactions)*. Arthralgias and muscle pain or weakness have also been reported in cases of proximal renal tubulopathy. Hypophosphatemia and

Brief Summary (Cont'd)

osteomalacia secondary to proximal renal tubulopathy should be considered in patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms while receiving products containing tenofovir DF *(See Warnings and Precautions).*

ADVERSE REACTIONS: Clinical Trials in Adult Subjects with Chronic Hepatitis B and Compensated Liver Disease: *Treatment-Emergent Adverse Reactions:* In controlled clinical trials in subjects with chronic hepatitis B (0102 and 0103), more subjects treated with VIREAD during the 48-week double-blind period experienced nausea: 9% with VIREAD versus 2% with adefovir dipivoxil. Other treatment-emergent adverse reactions reported in >5% of subjects treated with VIREAD included: abdominal pain, diarrhea, headache, dizziness, fatigue, nasopharyngitis, back pain, and skin rash. No significant change in the tolerability profile was observed with continued treatment with VIREAD for up to 384 weeks.

Laboratory Abnormalities: in Studies 0102 and 0103 (0–48 Weeks) laboratory abnormalities (Grades 3–4) reported in ≥1% of subjects treated with Viread (n=426) and adefovir dipivoxil (n=215), respectively, were: any ≥Grade 3 laboratory abnormality (19%, 13%); creatine kinase (M: >990 U/L; F: >845 U/L) (2%, 3%); serum amylase (>175 U/L) (4%, 1%); glycosuria (≥3+) (3%, <1%); AST (M: >180 U/L; F: >170 U/L) (4%, 4%); and ALT (M: >215 U/L; F: >170 U/L) (10%, 6%). Laboratory abnormalities (Grades 3–4) were similar in subjects continuing VIREAD treatment for up to 384 weeks in these trials.

The overall incidence of on-treatment ALT flares (defined as serum ALT >2 × baseline and >10 × ULN, with or without associated symptoms) was similar between VIREAD (2.6%) and adefovir dipivoxil (2%). ALT flares generally occurred within the first 4-8 weeks of treatment and were accompanied by decreases in HBV DNA levels. No subject had evidence of decompensation. ALT flares typically resolved within 4-8 weeks without changes in study medication. The adverse reactions observed in subjects with chronic hepatitis B and lamivudine resistance who received treatment with VIREAD were consistent with those observed in other hepatitis B clinical trials in adults. *Clinical Trial in Adult Subjects with Chronic Hepatitis B and Decompensated Liver Disease:* In a small randomized, double-blind, active-controlled trial (0108), subjects with CHB and decompensated liver disease received treatment with VIREAD or other antiviral drugs for up to 48 weeks. Among the 45 subjects receiving VIREAD, the most frequently reported treatment-emergent adverse reactions of any severity were abdominal pain (22%), nausea (20%), insomnia (18%), pruritus (16%), vomiting (13%), dizziness (13%), and pyrexia (11%). Two of 45 (4%) subjects died through Week 48 of the trial due to progression of liver disease. Three of 45 (7%) subjects discontinued treatment due to an adverse event. Four of 45 (9%) subjects experienced a confirmed increase in serum creatinine of 0.5 mg/dL (1 subject also had a confirmed serum phosphorus <2 mg/dL through Week 48). Three of these subjects (each of whom had a Child-Pugh score ≥10 and MELD score ≥14 at entry) developed renal failure. Because both VIREAD and decompensated liver disease may have an impact on renal function, the contribution of VIREAD to renal impairment in this population is difficult to ascertain. One of 45 subjects experienced an on-treatment hepatic flare during the 48 week trial.

Clinical Trials in Pediatric Subjects 12 Years of Age and Older with Chronic Hepatitis B: Assessment of adverse reactions is based on one randomized study (0115) in 106 pediatric subjects (12 to less than 18 years of age) infected with chronic hepatitis B receiving treatment with VIREAD (N = 52) or placebo (N = 54) for 72 weeks. The adverse reactions observed in pediatric subjects who received treatment with VIREAD were consistent with those observed in clinical trials of VIREAD in adults. In this study, both the VIREAD and placebo treatment arms experienced an overall increase in mean lumbar spine BMD over 72 weeks, as expected for an adolescent population. The BMD gains from baseline to Week 72 in lumbar spine and total body BMD in VIREAD-treated subjects (+5% and +3%, respectively) were less than the BMD gains observed in placebo-treated subjects (+8% and +5%, respectively). Three subjects in the VIREAD group and two subjects in the placebo group had significant (greater than 4%) lumbar spine BMD loss at Week 72. At baseline, mean BMD Z-scores in subjects randomized to VIREAD were −0.43 for lumbar spine and −0.20 for total body, and mean BMD Z-scores in subjects randomized to placebo were −0.28 for lumbar spine and −0.26 for total body. In subjects receiving VIREAD for 72 weeks, the mean change in BMD Z-score was −0.05 for lumbar spine and −0.15 for total body compared to +0.07 and +0.06, respectively, in subjects receiving placebo. As observed in pediatric studies of HIV-infected patients, skeletal growth (height) appeared to be unaffected *(See Warnings and Precautions).*

Postmarketing Experience: The following adverse reactions have been identified during postapproval use of VIREAD. Because postmarketing reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: allergic reaction, including angioedema, lactic acidosis, hypokalemia, hypophosphatemia, dyspnea, pancreatitis, increased amylase, abdominal pain, hepatic steatosis, hepatitis, increased liver enzymes (most commonly AST, ALT gamma GT), rash, rhabdomyolysis, osteomalacia (manifested as bone pain and which may contribute to fractures), muscular weakness, myopathy, acute renal failure, renal failure, acute tubular necrosis, Fanconi syndrome, proximal renal tubulopathy, interstitial nephritis (including acute cases), nephrogenic diabetes insipidus, renal insufficiency, increased creatinine, proteinuria, polyuria, asthenia. The following adverse reactions listed above, may occur as a consequence of proximal renal tubulopathy: rhabdomyolysis, osteomalacia, hypokalemia, muscular weakness, myopathy, hypophosphatemia.

DRUG INTERACTIONS: Didanosine: Coadministration of VIREAD and didanosine should be undertaken with caution and patients receiving this combination should be monitored closely for didanosine-associated adverse reactions. Didanosine should be discontinued in patients who develop didanosine-associated adverse reactions. When administered with VIREAD, C_{max} and AUC of didanosine increased significantly. The mechanism of this interaction is unknown. Higher didanosine concentrations could potentiate didanosine-associated adverse reactions, including pancreatitis and neuropathy. Suppression of $CD4^+$ cell counts has been observed in patients receiving VIREAD with didanosine 400 mg daily. In patients weighing >60 kg, the didanosine dose should be reduced to 250 mg once daily when it is coadministered with VIREAD. In patients weighing <60 kg, the didanosine dose should be reduced to 200 mg once daily when it is coadministered with VIREAD. When coadministered, VIREAD and didanosine EC may be taken under fasted conditions or with a light meal (<400 kcal, 20% fat). For additional information on coadministration of VIREAD and didanosine, please refer to the full Prescribing Information for didanosine. **HIV-1 Protease Inhibitors:** VIREAD decreases the AUC and C_{min} of atazanavir. Viread should not be coadministered with atazanavir without ritonavir. Lopinavir/ritonavir, atazanavir coadministered with ritonavir, and darunavir coadministered with ritonavir have been shown to increase tenofovir concentrations. Tenofovir disoproxil fumarate is a substrate of P-glycoprotein (Pgp) and breast cancer resistance protein (BCRP) transporters. When tenofovir disoproxil fumarate is coadministered with an inhibitor of these transporters, an increase in absorption may be observed. Patients receiving VIREAD concomitantly with lopinavir/ritonavir, ritonavir-boosted atazanavir, or ritonavir-boosted darunavir should be monitored for VIREAD-associated adverse reactions. VIREAD should be discontinued in patients who develop VIREAD-associated adverse reactions. **Drugs Affecting Renal Function:** Since tenofovir is primarily eliminated by the kidneys, coadministration of VIREAD with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of tenofovir and/or increase the concentrations of other renally eliminated drugs. Some examples include, but are not limited to cidofovir, acyclovir, valacyclovir, ganciclovir, valganciclovir, aminoglycosides (e.g., gentamicin), and high-dose or multiple NSAIDs *(See Warnings and Precautions).* In the treatment of chronic hepatitis B, VIREAD should not be administered in combination with adefovir dipivoxil.

USE IN SPECIFIC POPULATIONS: Pregnancy: *Pregnancy Category B:* There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, VIREAD should be used during pregnancy only if clearly needed. *Antiretroviral Pregnancy Registry:* To monitor fetal outcomes of pregnant women exposed to VIREAD, an Antiretroviral Pregnancy Registry has been established. Healthcare providers are encouraged to register patients by calling 1-800-258-4263. *Animal Data:* Reproduction studies have been performed in rats and rabbits at doses up to 14 and 19 times the human dose based on body surface area comparisons and revealed no evidence of impaired fertility or harm to the fetus due to tenofovir. **Nursing Mothers: The Centers for Disease Control and Prevention recommend that HIV-1-infected mothers not breastfeed their infants to avoid risking postnatal transmission of HIV-1.** Samples of breast milk obtained from five HIV-1 infected mothers in the first post-partum week show that tenofovir is secreted in human milk. The impact of this exposure in breastfed infants is unknown. Because of both the potential for HIV-1 transmission and the potential for serious adverse reactions in nursing infants, **mothers should be instructed not to breastfeed if they are receiving VIREAD. Geriatric Use:** Clinical studies of VIREAD did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for the elderly patient should be cautious, keeping in mind the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. **Patients with Impaired Renal Function:** It is recommended that the dosing interval for VIREAD be modified in patients with estimated creatinine clearance <50 mL/min or in patients with ESRD who require dialysis *(See Dosage and Administration).*

For detailed information, please see full Prescribing Information. To learn more call 1-800-GILEAD-5 (1-800-445-3235) or visit www.VIREAD.com.

Conference Alerts

North America

BIO CEO & Investor Conference
February 13-14, 2017 | New York, New York, USA

Website: https://www.bio.org/events/bio-ceo-investor-conference
Contact: register@bio.org

Now in its 19th year, the BIO CEO & Investor Conference is one of the largest investor conferences focused on established and emerging publicly traded and select private biotech companies. BIO CEO & Investor Conference presents a broad and unbiased view of investment opportunities. Each year the BIO CEO & Investor Conference provides a neutral forum where institutional investors, industry analysts, and senior biotechnology executives have the opportunity to shape the future investment landscape of the biotechnology industry.

The 2017 HIMSS Annual Conference & Exhibition
February 19-23, 2017 | Orlando, Florida, USA

Website: http://www.himssconference.org
Contact: himss@compusystems.com

The 2017 HIMSS Annual Conference & Exhibition brings together 40,000+ health IT professionals, clinicians, executives and vendors from around the world. Exceptional education, world-class speakers, cutting-edge health IT products and powerful networking are hallmarks of this industry-leading conference. More than 300 education programs feature keynotes, thought leader sessions, roundtable discussions and workshops, plus a full day of preconference symposia.

The 8th Annual CUGH Global Health Conference
April 7-9, 2017 | Washington, DC, USA

Website: http://www.cugh.org/events/2017-annual-cugh-global-health-conference
Contact: info@cugh.org

The CUGH Annual Conference has become the world's leading academic global health conference. The meeting brings together committed leaders, professionals, educators, students from diverse fields of study including engineering, business, law, policy, natural sciences, nursing, public health, medicine, and environmental studies to explore, discuss and critically assess the global health landscape. World-class speakers will address topics that include: planetary health; governance and political decision-making; health systems and human resources; women's health; non-communicable diseases and social determinants of health; and infectious diseases. Johns Hopkins University and Makerere University are serving as co-hosts for the Conference.

GHIC 2017: Global Health & Innovation Conference
April 22-23, 2017 | New Haven, Connecticut, USA

Website: http://www.uniteforsight.org/conference/
Contact: ufs@uniteforsight.org

The Global Health & Innovation Conference (GHIC) is the world's leading and largest global health conference as well as the largest social entrepreneurship conference, with 2,200 professionals and students from all 50 states and more than 55 countries. This must-attend, thought-leading conference convenes leaders, change-makers, and participants from all sectors of global health, international development, and social entrepreneurship.

Europe

31st International Papillomavirus Conference
February 28-March 4, 2017 | Cape Town, South Africa

Website: http://hpv2017.org
Contact: reg_hpv17@kenes.com

Through workshops, invited lectures, and oral and poster sessions presenting the latest research results, the conference will cover papillomavirus (PV)-related topics from basic science to global health impact. The conference themes will include the epidemiology and molecular biology of PVs; animal models for the study of papillomaviral disease; impact of the microbiome on HPV; basic immunology and pathogenesis of PVs; therapeutic and prophylactic vaccines; prevention of cervical cancer and other PV-associated diseases, and promotion of the spread of the scientific knowledge to benefit the whole community.

The 2017 World Congress Integrative Medicine & Health
May 3-5, 2017 | Berlin, Germany

Website: https://www.ecim-iccmr.org/2017/
Contact: esim@charite.de

This congress will take place in association with a number of international organizations including the Academic Consortium for Integrative Medicine and Health (ACIMH) in North America and others from around the globe. The main congress topics will include research, clinical care, education, traditional healing systems, and medicine and arts. Researchers, educators, policy makers and clinical providers of Complementary and Alternative Medicine (CAM) are all invited to take part in the conference.

Asia

12th Congress of Asia & Oceania Thyroid Association 2017
March 16-19, 2017 | Busan, South Korea

Website: http://www.aota2017.com/
Contact: office@aota2017.com

Tvhe congress will feature the latest advances in thyroidology as well as an update on the day to day practice of clinical thyroidology by renowned experts from the region. Since it had been established in 1975, Asia & Oceania Thyroid Association (AOTA) has grown rapidly and now it is one of the leading medical societies in Asia. At this congress, a number of thyroid experts from different Asian countries will bring together to exchange their scientific knowledge and build a strong networking with each other. These experts will highlight the peculiar nature of thyroid diseases in our region.

23rd International Conference on Oral and Maxillofacial Surgery
March 31-April 3, 2017 | Wan Chai, Hong Kong

Website: http://www.icoms2017.com/en/
Contact: icoms2017@llink.com.hk

The International Association of Oral and Maxillofacial Surgeons (IAOMS) is the largest global professional organization representing the specialty of oral and maxillofacial surgery. From its founding in 1962, the IAOMS has been a friendly community of oral and maxillofacial surgeons, bound together by a common enthusiasm for the well-being of their patients and the advancement of their specialty IAOMS has a rich conferencing history meeting every two years in cities around the world.

32nd International Conference of Alzheimer's Disease International
April 26-29, 2017 | Kyoto, Japan

Website: http://www.adi2017.org
Contact: adi2017@mci-group.com

The annual conference of Alzheimer's Disease International (ADI) attracts thousands of people with an interest in dementia from over 100 countries around the world. Hosted with a different Alzheimer association around the world each year, in 2017, the conference will be hosted with Alzheimer's Association Japan (AAJ). The conference is one of the world's largest and most important conferences on Alzheimer's disease and dementia, featuring a range of international keynote speakers and a high standard of scientific and non-scientific content; combined this makes it the optimum setting to learn about the latest advances in the treatment of dementia.

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1. Doctors Spending in Excess of $32,000 on Health IT

Doctors are spending more than $32,000 per year on health information technology (IT), according to an article published in Medical Economics. Results from the Medical Group Management Association (MGMA) survey suggest that medical groups spend more than $32,500 per year for every full-time doctor in their practice. Multisite practices incur additional costs for salaries of IT support staff and equipment, maintenance, and supplies. Between 2009 and 2015, costs for IT increased by 40 percent, with the biggest increases seen in 2010 and 2011; costs can be expected to continue increasing at considerable rates. IT plays a crucial role in helping health care organizations to evolve in order to provide higher quality, value-based care, and physicians are looking to use technology to improve practice management and to avoid government meaningful use penalties.

http://medicalxpress.com/news/2016-10-doctors-excess-health.html

2. New Drug Target for Asthma, Autoimmune Disorders Identified

Using a new tool for probing the molecular makeup of cells, researchers have discovered that PD-1 - a marker that already serves as a drug target for some cancers - may also serve as a drug target for asthma and other autoimmune disorders. The researchers, led by a group from the Wellcome Trust Sanger Institute in the United Kingdom, report their work in the journal Nature. In the new study, the researchers examine a recently discovered group of cells in the immune system called innate lymphoid cells (ILC cells). Within this group, there is a subgroup called ILC2 cells that influences immune responses during infections and asthma.

http://www.medicalnewstoday.com/articles/313263.php

3. A Stem Cell Gene Found to Command Skeletal Muscle Regeneration

Prox1 gene has long been known to play an important role in fetal development. Finnish researchers have now discovered that Prox1 is essential also for skeletal muscle stem cell differentiation. Skeletal muscles are important not only for locomotion but also for the regulation of whole-body metabolism. Muscles have remarkable capacity to regenerate after injury and to adapt in response to exercise training. Researchers from Wihuri Research Institute and the University of Helsinki, Finland, have now found that skeletal muscle stem cells called satellite cells also express the Prox1 gene. The new surprising results of the study, published in Nature Communications, show that satellite cells differentiate into myofibres only when Prox1 is active.

https://www.sciencedaily.com/releases/2016/10/161012095822.htm

4. G.O.P. Plans to Replace Health Care Law with ‘Universal Access’

House Republicans, responding to criticism that repealing the Affordable Care Act would leave millions without health insurance, said that their goal in replacing President Obama’s health law was to guarantee “universal access” to health care and coverage, not necessarily to ensure that everyone actually has insurance. In defending the Affordable Care Act, the Obama administration, congressional Democrats and advocacy groups have focused on the 20 million people covered by the law, which has pushed the percentage of Americans without health insurance to record lows. The American Medical Association recently said that “any new reform proposal should not cause individuals currently covered to become uninsured.”

http://nyti.ms/2hU5WIm

5. Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits

Dr. Belldegrun, a physician, co-founded Kite Pharma, a company that could be the first to market next year with a highly anticipated new immunotherapy treatment. But even without a product, Dr. Belldegrun has struck gold. His stock in Kite is worth about $170 million. Investors have profited along with him, as the company’s share price has soared to about $50 from an initial price of $17 in 2014. The results reflect widespread excitement over immunotherapy, which harnesses the body’s immune system to attack cancer and has rescued some patients from near-certain death. But they also speak volumes about the value of Kite’s main scientific partner: the United States government.

http://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html

6. States Sue Generic-Drug Companies over Price-Fixing Allegations

Twenty state attorneys general sued a group of generic-drug companies Thursday, accusing them of colluding to fix prices on an antibiotic and a diabetes medication, in violation of federal antitrust law. The suit comes a day after price-fixing charges against former executives at one of the drug makers were unsealed in a Justice Department antitrust probe. The attorneys general, including Connecticut’s George Jepsen and New York’s Eric Schneiderman, alleged in a suit filed in Connecticut federal court that six companies conspired to manipulate prices for doxycycline hyclate, an antibiotic, and glyburide, used in the treatment of diabetes.

http://www.wsj.com/articles/states-sue-generic-drug-companies-over-price-fixing-allegations-1481820123

7. U.S. Health Spending in 2015 Averaged Nearly $10,000 per Person

Total spending on health care in the United States increased last year at the fastest rate since the 2008 recession, reaching $3.2 trillion, or an average of nearly $10,000 a person, the Department of Health and Human Services reported. The growth coincided with continuing increases in the number of Americans with insurance coverage, through private health plans or Medicaid. Federal spending on health care has increased by 21 percent over the past two years, as millions of Americans gained coverage through the Affordable Care Act, the department said in its annual report on health spending.

http://nyti.ms/2gvMB2y

8. Johnson & Johnson Must Pay 6 Implant Patients $1 Billion

A federal jury in Dallas on Thursday ordered Johnson & Johnson and its DePuy Orthopaedics unit to pay more than $1 billion to six plaintiffs who said they were injured by Pinnacle hip implants, a lawyer for the plaintiffs said. The jurors found that the metal-on-metal Pinnacle hip implants were defectively designed, and that the companies did not warn consumers of the risks. The six plaintiffs are California residents who were implanted with the hip devices and experienced tissue death, bone erosion and other injuries they attributed to design flaws. The plaintiffs claim the companies promoted the devices as lasting longer than devices that include ceramic or plastic materials. Johnson & Johnson and DePuy are facing nearly 8,400 Pinnacle-related lawsuits, which have been consolidated in federal court in Texas. Test cases have been selected for trial, and the outcomes will help gauge the value of the remaining claims.
http://nyti.ms/2gS48z2

9. Expect Medicaid to Change, but Not Shrivel, Under Donald Trump

The expansion of Medicaid, a central pillar of the Affordable Care Act, faces immense uncertainty next year, with President-elect Donald J. Trump and top Republicans in Congress embracing proposals that could leave millions of poorer Americans without health insurance and jeopardize a major element of President Obama's legacy. But influential figures in surprising quarters of the new administration might balk at a broad rollback of Medicaid's reach, favoring new conditions for access to the government insurance program for the poor but not wholesale cutbacks. Mike Pence, the vice president-elect, is proud of the Medicaid expansion he engineered as governor of Indiana, one of 31 states that expanded eligibility under the Affordable Care Act. The Indiana program has conservative features that emphasize "personal responsibility" and require Medicaid beneficiaries to make monthly contributions to savings accounts earmarked for health care.
http://nyti.ms/2eX6CuJ

10. Merck Snags Record $2.54B in Second Hep C patent Verdict Against Gilead

An ongoing patent infringement battle between Merck and Gilead over the latter's hepatitis C blockbusters, Harvoni and Sovaldi, has swung back in Merck's favor. A federal jury in Wilmington, Delaware, yesterday rejected Gilead's claim that Merck's patent, issued in 2009, is invalid and ordered Gilead to pay Merck $2.54 billion—the equivalent of 10% royalties on Harvoni and Sovaldi. It was the largest verdict in a patent-infringement case in U.S. history, according to Bloomberg, and it came just four months after a different court ruled against Merck in a separate patent battle involving Gilead's hep C crown jewels.
http://www.fiercepharma.com/pharma/merck-snags-record-2-54b-hep-c-patent-verdict-against-gilead

11. Allergan eyes depression as blockbuster Botox's next big stage

Allergan's planning to keep the label expansions coming for blockbuster Botox, which already boasts a range of indications in both the therapeutic and aesthetic spheres. And the company is eyeing depression as the product's next frontier. The Dublin drugmaker is wrapping up a phase 2 study of its star, based on investigator-initiated trials done in Germany that showed a single administration of Botox could match other antidepressants from an efficacy standpoint. Allergan anticipates getting its hands on the data at some point next year, and if it can replicate the German findings, "it's going to be really valuable in psychotherapy, no doubt," company R&D chief David Nicholson told FiercePharma in an interview.
http://www.fiercepharma.com/node/364301

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