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WKMJ

World Korean Medical Journal

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WKMO Fall Concert 2015

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FROM THE PUBLISHER

Dear Colleagues,

Hope everyone is well as the holidays are approaching. In this issue we feature two remarkable figures in Heath care. One is Dr. David Song, an academic plastic surgeon with an endowed chair. He is Professor at University of Chicago where he is heavily involved in teaching being residency director and associate dean for continuing medical education. As academic plastic surgeons the scope of care is quite broad but involve patients with congenital deformities, but also burn victims and cancer patients who need the skills to make the surgeries necessary to make the patient feel more whole. His research interest is in the plastic surgery of oncologic patients. He is the first Asian/Korean to be president of the American Society of Plastic Surgeons which is quite an accomplishment and wants to promote the field as a field beyond the cultural stereotype. He is very forward thinking utilizing social media which is progressive and will have a wider role in medicine. Plastic surgery is a medical specialty with an edge of artistry. Korean plastic surgeons are known to be highly skilled in their craft. Hope much success for his term for the American Society Plastic Surgery.

The other healthcare figure feature in this issue is Paula Wilson. She is President of the Joint Commission International (JCI). The JC is a very important accreditation organization in U.S. Healthcare with onsite inspection of hospitals assures standards and quality which has been in existence since the 1950's. The JC international is a more recent development but is an opportunity for hospitals throughout the world to assure high stand and quality and a number of hospital in Korea have this prestigious accreditation and the list will grow. JCI will be more involved in global healthcare, and will be challenging in the developing countries as resources may be more limited but the standards will be the same.

As the end of the year is approaching it is time of reflection and WKMO has been busy. The regional forum in London, UK was reaching out to the European continent and the English-Korean medical collaboration kick started by KHIDI UK is well underway to the benefit of two very successful and efficient healthcare systems. The annual meeting in Los Angeles was very intriguing with TED style talks which were very stimulating with Neurology, Psychiatry and Imaging forums. Congressman Mike Honda of San Jose was the humanitarian awardee for his leadership in Korean Comfort women issue as well as his efforts with hepatitis in the Asian population. Like to thank the all the sponsors including Samsung and KHIDI. A big thanks goes to Dr. Chul Hyun, the staff of WKMO and editorial sraffs of World Korean Medical Journal. Look forward to a productive 2016. Happy Holidays to you and your family.

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

FROM THE EDITOR-IN-CHIEF

In her fascinating book titled "The Making of Asia America : A History (2015)", an award-winning American historian and the Director of the Immigration History Research Center at the University of Minnesota, Erika Lee tells the little-known history of Asian Americans and their role in American life, from the arrival of the first Asians in the Americas to the present-day. She wrote "we were a despised minority when Asian immigrants threatened 19th century and early 20th century white labor".

Yet since the Cold War, Asian Americans were described as a Model Minority valorizing the promise of American meritocracy. Maybe 'Asian Americans' are the unique ethnic group in American history which changed its socioeconomic status so rapidly. Sociology professor Jennifer Lee of University of California, Irvine, claims that it isn't Asian "culture" or any other attribute of ethnicity that is responsible for Asian Americans achievements or success. Instead, it's a unique form of privilege that is grounded in the socioeconomic origins of some - not all - Asian immigrant groups.

We witness this privilege in many success stories of Asian Americans including medical fields, and sharing such stories may offer insights into how we should help our children and communities.

As the Cover Story of the November edition, we featured another passionate achiever and inspiring leader in the medical arena. Dr. David H. Song, the president of American Society of Plastic Surgeons (ASPS) as the first Asian American physician was introduced. Under his leadership, ASPS will take care of patients with congenital deformities, like cleft lip/palate, burn victims, hand trauma, reconstruction after cancer and much more. He mentioned that plastic surgery is in essence of a field of innovative problem solving and remains one of the last specialties that solve problems all over the body and he will broadcast this message with clarity during his year as the president.

In our Entrepreneur Interview, we meet Paula Wilson of Joint Commission International. Having long experience as a teacher and professor, she advises that a good leader needs to be a good teacher. Communicating about the vision and strategy of an organization with colleagues and inspire them to get the work done, is the similar essence of what teaching demands.

New trends and issues of bio-health industry were featured in the articles. Special reports of WKMO and global initiative of a clinical-stage biotech Enzychem Lifesciences of Korea were featured.

Many distinguished writers shared their knowledge and insights in this edition. I wish that our readers will find this exciting selection of articles to be helpful and inspiring.

Thank you.

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

WKMJ RECAP OF AUGUST ISSUE

Cover Story
Inspirational Korean Healthcare Leader "Dr. Chul S. Hyun, Inaugural President of World Korean Medical Organization"

Dr. Chul S. Hyun is the president of World Korean Medical organization, a global network of 140,000 physicians of Korean descent s. He is also the director general of CVH (Center for Viral Hepatitis). He is board certified in Internal Medicine and Gastroenterology and has been an attending gastroenterologist in New York Presbyterian Hospital where, he currently serves as a clinical faculty in the Division of Gastroenterology and Hepatology at the Will Cornell Medical College. To read more about Dr. Hyun's successful physician story read Issue 7.

Special Report
the 3rd New York Health Forum

On May 21, 2015, the third New York Health Forum titled, "Future is Now: The Era of Mobile Health" was held at the Explorer's Club in Manhattan. At forum experts discussed unrealized potential of mobile health, one of the hottest topics for speculation in healthcare today. Mobile health can dramatically transform the way healthcare is sought and delivered. For more detailed report on the third New York Health Forum, please refer to Issue 7, to find out more.

Biopharmaceutical Report 1
US Rheumatologists' View on Biosimilars

Experts agreed they are not concerned about biosimilars having unanticipated adverse effects. Their concern lies in the belief that, until biosimilasr have entered the market on a large scale, it will be difficult to determine the extent of their bioequivalence. Experts are waiting to see how it plays out once biosimilars enter the US market and how to sort out regulatory issues. For more detailed report about biosimilars, read Issue 7 to find out more.

Biopharmaceutical Report 2
Seattle Genetics/Takeda's Adcetris, Likely to Get Label Expansion

Seattle Genetics and Takeda Pharmaceutical's Adcetris will likely get a Hodgkin's Lymphoma (HL) label expansion from the FDA based on results of the AETHERA study, experts said. The Phase III trial's (NCT01100502) positive results on the primary endpoint of progression-free survival (PFS) in patients who are at high risk of relapse following autologous stem cell transplant (autoSCT) make approval likely. Read Issue 7 to find out more.

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Inspirational Korean Healthcare Leader

Dr. David H. Song, the University of Chicago Surgeon Appointed as the President of the American Society of Plastic Surgeons

Photo by Bruce Powell

1. Dr. Song, you are world-renowned successful plastic surgeon. What was your motivation to become a doctor and did you face any significant troubles or obstacles during your physician life?

- Like many Korean/American children, growing up to be a doctor was a cultural goal, however, I was more interested in classical studies, political science and literature. Then in 11th grade science class, I was introduced to a Vascular Surgeon who gave a riveting presentation and what he showed was transformative for me. The vascular anatomy and the ability to bypass areas of occlusion with donor vein and suture blood vessels together left an indelible image in my mind. I always enjoyed building models and using my hands for intricate work and the ability to do intricate work while saving a person's life or limb resonated with me. At that moment, I felt I had to pursue a career in medicine. I enrolled in the highly competitive 7 year undergraduate/ medical school program at UCR/UCLA and didn't quite realize that out of 385 people accepted to start, only 24 would actually graduate from medical school. This highly competitive world was new to me and it was then that I questioned my desire to be a doctor. The long nights of studying and intense competition made it difficult for me to see the final goal of being a doctor. I also minored in classical studies and at one point contemplated changing my career path to pursue the classics. In the end, the pull of a career in medicine was strong and I graduated medical school from UCLA and matched into general surgery at The University of Chicago. This was a period of intense growth and focus as I trained in an era prior to the 80-hour workweek. Like many residents at that time, there were weeks where I worked in the hospital well over 120 hours and slept very little, but being in the operating room was a natural fit for me. These are hurdles everyone training to be a doctor has overcome and are not unique to me.

Dr. Song in the operating room *Photo by Danilo Diaz*

COVER STORY

2. You've become the president of American Society of Plastic Surgeons as the first Asian American physician. Can you say a few words on being elected and share your vision and goal as a leader of group?

Dr. Song, operating on a patient *Photo by Danilo Diaz*

- It is an incredible honor to be elected as president of the American Society of Plastic Surgeons. It is the largest society of plastic surgeons in the world and the clear voice of our specialty. I take pride in being the first Asian/American president, and feel a great sense of responsibility to represent our specialty as a Korean American. We have a strong agenda during this year to further educate the public on what it means to be a Board Certified Plastic Surgeon and a goal of engaging the public further via social media. I'm active on Twitter (@ DrDavidSong) and Instagram and feel that Social Media is an important and powerful tool when used correctly to educate and share with the public the importance of what we do as Plastic Surgeons. Cosmetic surgery is what the public mostly thinks of when discussing plastic surgery, and we are clearly the sine qua non of Cosmetic Surgery, but Plastic Surgery encompasses so much more. We take care of patients with congenital deformities, like cleft lip/palate, burn victims, hand trauma, reconstruction after cancer and much more. Plastic Surgery is in essence a field of innovative problem solving and remains one of the last specialties that solve problems all over the body. I hope to broadcast this message with clarity during my year as president.

Dr. Song presenting visions and plans of the University of Chicago Medicine to the audience

3. All parts of clinical process should be difficult and careful but communicating with patient must be particularly difficult. What is the most important aspects when you communicate with patients and how do you manage your communication with them?

- Accurate and empathic communication is the fundamental building block of a successful doctor patient relationship. For me I take great pride in engaging with my patients and treating each and every patient as if they are a member of my family. Once a doctor keeps this mindset, then communication becomes enriched and patient care is enhanced. Surgeons often are not perceived as the best communicators and for me I always wanted to change that perception as a resident. Given the ever increasing pressures and time constraints on doctors today, it is difficult to maintain this personal touch, but not impossible. All my patients have direct access to me as I give out my email and cell phone. This sense of knowing that they can always reach me is comforting to them and helps me to be pro-active with any possible issues that may arise. To me, this equates to the best personal care possible in this new era.

4. We've learned that your research interests focus on outcome improvement in lumpectomy and mastectomy reconstruction and you are involved in several clinical trials exploring advancements in these procedures. How do your collaborate with industry side and what's your opinion on such collaboration?

- Industry continues to be an important partner in innovation of medicines, devices and overall health care delivery. In this new era of transparency, it is critical that physicians maintain an ethical and open structure with industry relationships. With this transparency, innovation can and will still continue to be fruitful. Some examples of industry relationships come in the form of unrestricted educational grants that help to drive education, training and innovation yet keep an arms length from the actual data that the grants may be funding and thus help to keep the results unbiased.

5. The University of Chicago Medicine is well known teaching hospital. You're an internationally recognized plastic surgeon and at the same time you also had the responsibility as Director of Residency Training Program. How do you view yourself as an educator and what are the core values that you teach your trainees?

- Without a strong sense of responsibility for training the next generation of plastic surgeons, an academic career loses much of its impact and meaning and thus education and training residents is in and of itself a central mission of mine. My style of educating is one of mentorship. While we have a strong and rigorous curriculum, I value the importance of life mentorship. Our residents are an extremely intelligent and accomplished group of young doctors, so knowledge acquisition is an innate part of who they already are and thus I strive to guide and focus them on decision making both in and out of the operating room. Nurturing and developing their emotional intelligence is very important to me so I share with my residents the style of conversations I have with patients and colleagues when navigating through conflict resolution, shared goal setting and attaining a win-win with each challenging encounter. Leadership is changing and the effective leaders of tomorrow are those who not only possess knowledge and skill, but also have a keenly developed sense of self-awareness and high emotional intelligence. In my opinion, mentoring in this fashion will help equip them to be future leaders of our field.

Dr. Song giving words after being elected as president of ASPS

6. We understand that the University of Chicago Medicine has been very active internationally, bringing in many international patients to Chicago and expanding its brand to other countries. What is your vision on the global healthcare?

- The world today is much smaller than it was even 10 years ago. Patients have choices not only in their region or country, but internationally. We at the University of Chicago Medicine fully understand this and aim to be not only the best global medical center, but also one that is culturally respectful and sensitive to the nuances of all our patients' needs and preferences. We have a robust and growing international healthcare department and receive and treat patients from all over the globe. With this platform, our outreach efforts continue to expand and as we leverage our technologies, we look forward to having international healthcare become an ever-increasing component of our Center for Care and Discovery.

Dr. David Song

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

- It is a tremendous honor to be highlighted in WKMJ amongst my peers in Medicine. I hope to carry this honor throughout my presidency of the American Society of Plastic Surgeons and beyond; further shedding light onto the great contributions doctors of Korean decent have made and continue to make in Medicine.

David H. Song, MD

Vice-Chairman, Department of Surgery at the University of Chicago Medicine
President, American Society of Plastic Surgeons

David H. Song, MD, is an internationally recognized expert in plastic surgery with additional training in reconstructive microsurgery. He specializes in breast reconstruction and oncoplastic surgery. He is the Cynthia Chow Professor of Surgery, vice chairman of the Department of Surgery, chief of Plastic Surgery, and associate dean for Continuing Medical Education at the University of Chicago Medical Center. In 2005, Dr. Song was name to Crain's Chicago Business' list of 40 high achieving executives younger than age 40. Song is well recognized for his extensive experience with perforator breast reconstruction procedures, including deep inferior epigastric perforator flap (DIEP), superior gluteal artery perforator flap (SGAP), superficial inferior epigastric artery flap (SIEA), thoracodorsal artery perforator flap (TAP) and the uses of acellular dermal matrix (AlloDerm) to enhance implant breast reconstruction and reconstruct abdominal wall defects. Additionally, he has pioneered and invented several techniques for the repair and reconstruction of chest wall defects. Dr. Song severs on the board of Medical Aid for Children of Latin America (MACLA), and past president of the Chicago Society of Plastic Surgeons. Currently, Dr. Song serves as president for the American Society of Plastic Surgeons (ASPS).

Paula Wilson paneling the 3rd New York Health Forum (NYHF)

Ms. Wilson networking with Dr. Chul Hyun

Entrepreneur Interview

Paula Wilson, President and Chief Executive Officer of Joint Commission Resources and Joint Commission International

1. Although many of our readers would be familiar with Joint Commission and Joint Commission International, please explain your organizations' structure, function, mission and activities with our readers.

The Joint Commission is an independent, not-for-profit organization that accredits and certifies health care organizations and programs in the United States. Joint Commission accreditation and certification is recognized throughout the US as a symbol of quality that reflects an organization's commitment to meeting certain performance standards. The mission of The Joint Commission is to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value. In 1994, The Joint Commission extended this mission outside the United States with the creation of Joint Commission International (JCI).

Joint Commission International provides leadership and innovative solutions to help health care organizations across all settings improve performance and outcomes. Expert teams work with hospitals and other health care organizations, health systems, government ministries, public health agencies, academic institutions, and businesses to achieve peak performance in patient care.

JCI helps organizations to help themselves through:

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- Providing leading education

2. JCI is working to improve health care quality and patient safety around the world. We assume that healthcare systems in each country must have various differences based on country's culture, system, and people. How do you manage to overcome cultural barriers and offer right directions for healthcare providers in each country?

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There is much that is universal about safe practices in health care, and we share this across borders throughout the world. We are also pay careful attention to cultural differences and have implemented this through regional offices and staff.

We understand that local needs vary and diverse cultures present unique patient care challenges. Yet, our singular focus on the highest patient care standards and results-oriented process improvement has earned the respect of health care leaders from around the world.

3. As the leader of JCI and healthcare service industry's key opinion leader, where do you think the healthcare service industry is headed? What do you think is the most important issue in the industry?

The biggest issue facing the healthcare service industry is delivering high quality, affordable services, safely. This is especially important as virtually all parts of the world are seeing older populations with rapidly growing rates of chronic disease. Private and public payers are expecting better value from providers and health care leaders are feeling this pressure.

Ms. Wilson speaking on topic of current status challenges, and opportunities of mobile Health at NYHF

Dr. Joe McMenamin, Executive Vice President of WMSG and Ms. Wilson

4. There are over 24 healthcare providers in South Korea which have been accredited by JCI. What are JCI's business strategies in Asian region including Korea? How do you value East Asian countries and their healthcare providers?

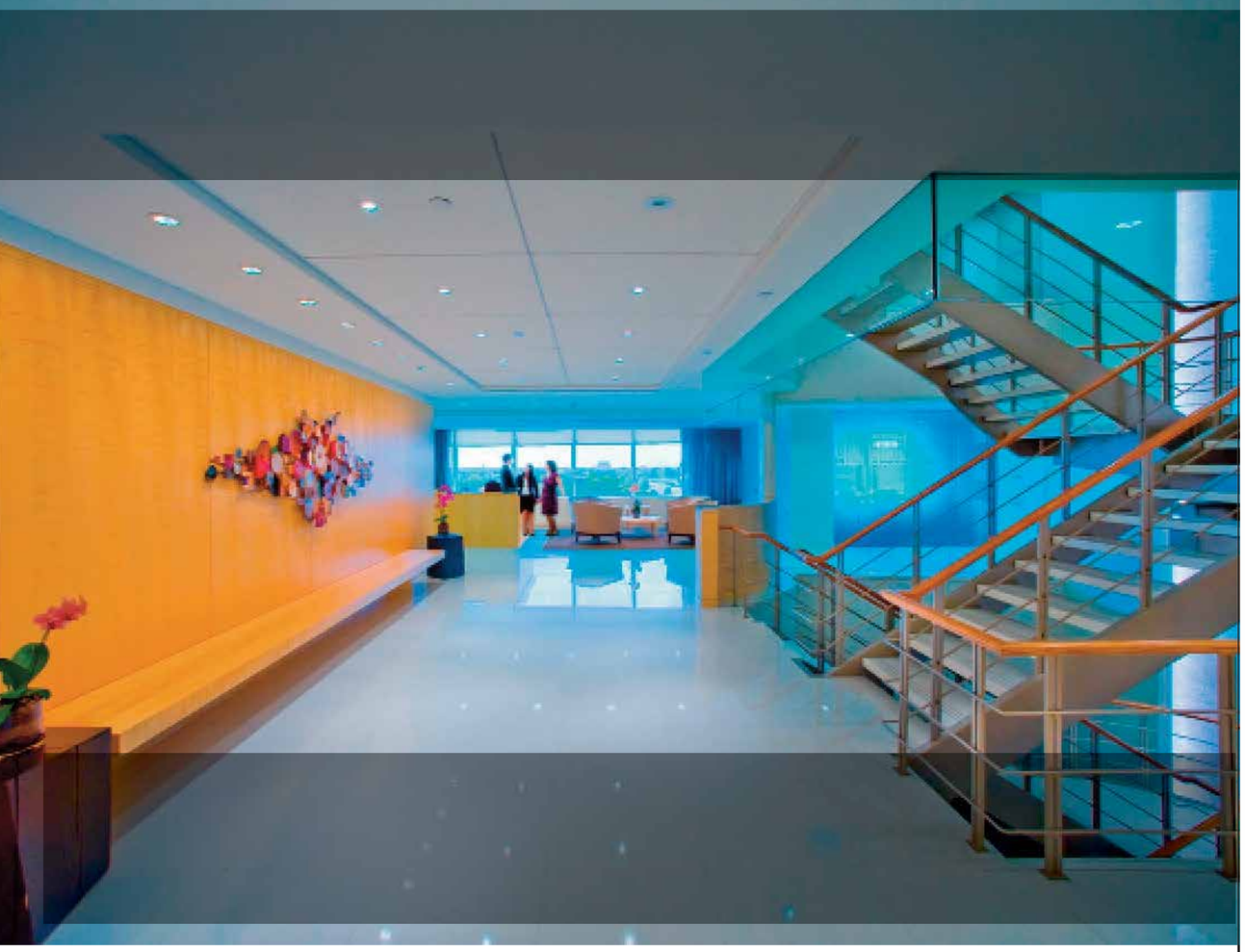
The east Asian countries present a unique opportunity, with the dichotomy of both the emerging economies and emerged economies working side by side. JCI has a very strong focus in East Asia, including Korea. Our goal is to partner with healthcare organizations who want to embark on the journey of continuous improvement in patient safety and quality. At the same time we are also in discussions with the Ministries of Health to look at opportunities to create awareness through education, consulting services to help upgrade the health services as well as to build capabilities in the region and also to raise the bar to be at par with western economies.

Healthcare providers are making rapid progress especially in the private sector with a lot of investment in new hospitals and in emerging markets. It is encouraging to see new hospitals are looking for international accreditation as they are being built. We are investing time and effort in the region to be part of this journey of continuous improvement for patients safety and quality.

5. You have long teaching experiences including teaching at Columbia University and New York University. Teaching students and managing huge entities seems very different tasks to conduct. How did you transit yourself from an educator to a business leader? Or how do you manage to combine all those experiences synergistically?

My transition from an academic environment to running a business was relatively smooth. It was made easier by the fact that I held fairly large management positions earlier in my career, before I became a college professor. Also, I believe that a good leader needs to be a good teacher. Leaders need to be able to communicate the vision and strategy of an organization to the people who work there. They need to be inspiring to the work force and other constituencies with the operational discipline to get the work done. This is very similar to the essence of what a teacher does in the classroom. W

Ms. Wilson and Dr. Seung Han Suk, President of Korean Institute of Healthcare Accreditation handshaking at the MOU Ceremony



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SPECIAL REPORT I

KOREA'S ENZYCHEM LIFESCIENCES LAUNCHES NEW GLOBAL INITIATIVE

SPECIAL REPORT II

WKMO FALL CONCERT 2015

Special Report I

Korea's Enzychem Lifesciences Launches New Global Initiative

MOU was signed by Enzychem Lifesciences and W Medical Strategy Group in NYC last October

Korea's leading Sohn biopharmaceutical company Enzychem Lifesciences (CEO and Chairman SOHN Ki-Young) has launched its major global initiative in the United States. The initiative will help facilitate licensing, strategic partnerships and investment opportunities for self-developed global new drug candidate EC-18's development and commercialization as the innovative therapeutic.

EC-18, a synthetic monoacetyldiaglyceride, is the world's first oral medicine candidate to prevent and treat chemotherapy-induced neutropenia (CIN) with unique MOA (mechanism of action) different from G-CSF, and U.S. FDA already has cleared the company's Investigational New Drug application (IND). Korean government, through its striving global new drug development initiative 'Korea Drug Development Fund', also granted Enzychem and EC-18 to further its clinical trials with assenting support from the government. New approaches are needed to improve CIN patient treatment beyond the current standard of care and launching of this first-in-class therapy could star in future combination treatments.

Focused on developing innovative, cost-effective treatment, Enzychem is confident that EC-18 can address significant unmet medical needs, and also highly anticipated to be designated as break through therapeutic by U.S. FDA. Breakthrough designation is a process intended to expedite the development and review of drugs for serious or life-threatening conditions and the criteria for designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

Enzychem is also focusing on promoting its immune-modulatory health functional food ROCKPID. ROCKPID is a Korean Food and Drug Administration approved supplement which has active ingredient PLAG, effective in modulating the human immune system.

Following the vision of Enzychem Lifesciences founder and Chairman Sohn -- to contribute to the health and happiness of humanity at large by saving human lives one at a time -- Enzychem is ready to take part in global biopharmaceutical innovation that develops new drugs to fulfill essential yet unmet needs of patients.

To realize this mission, Enzychem Lifesciences recently completed a MOU with W Medical Strategy Group, a New York based consulting firm with diverse medical and pharmaceutical networking portfolio, to further explore US strategic partnerships and investment opportunities.

Enzychem Lifesciences meets with a financial institution in NYC

Enzychem Lifesciences presents at 4th New York Health Forum in NYC with attendance of 80 global pharma BD executives

Enzychem Lifesciences presents at Physicians Seminar Network in NJ with attendance of 30 U.S physicians

Sangji Lee

Executive Director, Business Development

W Medical Strategy Group

Sangji is Executive Director of Business Development at W Medical Strategy Group. Sangji also is secretariat staff of WKMJ editorial. Prior to joining WMSG, she was a researcher at Korea Health Industry Development Institute USA, representing Ministry of Health of Korea.

Special Report II

WKMO Fall Concert 2015

A special WKMO Gala took place on October 31, 2015, in Palisades, New York!

Soprano singer Haeran Hong and Tenor Won Whi Choi performing their duet musics

Organized and sponsored by World Korean Medical Organization and Korean American Civic Empowerment, this event honored Congressman Mike Honda from California. Congressman Honda is especially well known to Korean community for his pioneering work on House resolution 121, which expressed the sentiment of the Congress that Japan should formally acknowledge, recognize, and accept historical responsibility in an unequivocal manner for its Imperial Armed Forces' coercion of women into sexual slavery. For his humanitarian and legislative efforts,

Dr. Ko giving his welcoming address

Congressman Mike Honda and concert attendee

Dr. Hyun speaking before the concert about purposes and meaning of the event

Congressman Honda was recognized in 2013 with the WKMO Humanitarian Award. He is also well known for his leading work on viral hepatitis B and other health care disparity issues in the United States. WKMO was privileged to have him as a keynote speaker in 2015 WKMO Convention in Los Angeles.

Dr. Chul S. Hyun, the past president of WKMO gave a welcoming remark. Congressman Mike Honda spoke about the House resolution 121 and Health Access for ethnic minority populations in the United States. WKMO's new president, Dr. David Ko presented future plans on WKMO activities, including 2016 Summer Convention.

One of the highlights of the gala was the Music Concert. WKMO invited world renowned Tenor Won Whi Choi and Soprano Haeran Hong from Germany who presented extraordinarily beautiful performance to the attendees. It was truly a memorable evening celebrating the success and leadership in health care and human rights.

The gala was also attended by many other distinguished guests, including Dr. & Mrs. Stanley Shin (Atlanta, GA), Dr. & Mrs. Thomas Moon (Englewood Cliffs, NJ), Dr. Alice Chu (Clifton, NJ),and Dr. & Mrs. Henry Lee (New York, NY).

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Happy smile and hope after pain

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

Cancer-free D.K. Lee

D.K. Lee attending
beauty classes while chemotherapy treatment

No Differentiation Expected Among PARP Inhibitors

PARP inhibitors like Tesaro's (NASDAQ:TSRO) niraparib, Clovis Oncology's (NASDAQ:CLVS) rucaparib and AstraZeneca's (LON:AZN) approved Lynparza (olaparib) will find it tough to differentiate from one another, experts said.

Since they are thought to have comparable efficacies, the type and nature of side effects may be the main distinction, they noted. The side effect profiles, however, are not yet showing much separation, they said.

And while niraparib and rucaparib may have the upper hand compared to Lynparza since the former two are being studied in a broader population, Tesaro's and Clovis' biomarker strategy somewhat similar to each other, experts add.

Lynparza is approved only for patients who carry a germline BRCA mutation, while niraparib is being studied in a larger group of patients who have homologous recombination deficient (HRD) tumors and are said to constitute around 40-60% of all ovarian cancer patients, experts added. Rucaparib is relying on an approach that considers sensitivity based on an loss of heterozygosity (LOH) score derived from genome wide LOH driven by HRD mutations. This is said to include over 65% of patients who have either BRCA mutations or are classified as BRCA-like, according to a Society of Gynecologic Oncology 2015 presentation.

Lynparza received an FDA nod on 19 December 2014 for patients who have received at least three lines of chemotherapy based on subset efficacy data from a single-arm, open label Phase II study. The EMA approval in the maintenance setting was based on the overall Phase II trial, which the FDA's Oncologic Drugs Advisory Committee had voted against.

Lynparza is being studied in the maintenance setting for patients following first-line platinum therapy and platinum-treated relapsed patients with BRCA mutations in Phase III SOLO1 and SOLO2 trials, respectively.

While maintenance setting data from Tesaro's NOVA Phase III trial are expected in 4Q15, Clovis plans to release Phase III Ariel3 results in 1H16.

Side-effect profile may be separator since efficacy is comparable

The side-effect profiles may have a role in differentiating one PARP from another, said Dr Brian Slomovitz, division director, Gynecologic Oncology University of Miami Health System. While there's no major comparable difference right now between the different PARP inhibitors, they might stand out eventually once the drugs have been in use for long, he added.

In niraparib's Phase I trial, the only completed clinical study, Grade 4 thrombocytopenia was a dose-limiting toxicity for ovarian cancer patients at 400 mg QD, while other side effects across other indications included Grade 1-2 fatigue, anorexia, nausea and myelosuppression. The Phase III trial is evaluating niraparib at a 300 mg QD dose.

In the 204-patient Phase II Ariel2 trial with rucaparib, 11% had elevated AST/ALT (aspartate transaminase/alanine transaminase), 19% patients had anemia or decreased hemoglobin and 15% of patients experienced fatigue among Grade 3-4 adverse events, according to a European Society for Clinical Oncology 2015 presentation.

Based on adverse event (AE) reports evaluated by the FDA for Lynparza, 0.8% (21/2618) of patients reported having myelodysplastic syndrome/ acute myeloid leukemia versus 1.3% (2/160) of those on placebo, according to an FDA Advisory committee document.

From the data it would seem like there's less genomic toxicity with the rucaparib, since myelodysplasia has not been observed, said Penson.

It is not clear which PARP inhibitor has more bone marrow toxicity than others, but while other side effects like Grade 1-2 nausea, fatigue or elevation of liver enzymes would be considered manageable, myelodysplasia is something that is being closely watched for, particularly in the maintenance setting, said Dr Alan D'Andrea, Alvan T. and Viola D. Fuller American Cancer Society professor of Radiation Oncology, Harvard Medical School, Boston. Oncologists have learned to manage side effects like nausea and other gastro-intestinal (GI) related effects, said Dr Emmanouil Saloustros, attending physician, General Hospital of Heraklion "Venizelio-Pananio", Greece.

Price Reduction similar to Europe anticipated

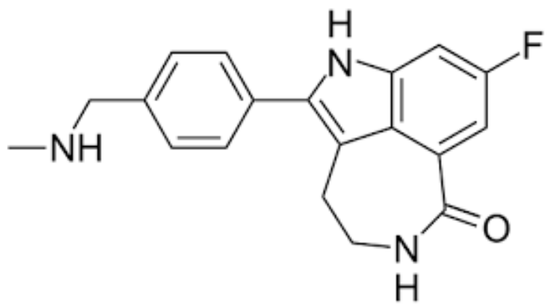
In the maintenance setting, PARP inhibitors are generally well tolerated and relatively easy to give, said Dr Richard Edmondson, chair, Gynecological Oncology, Faculty Institute for Cancer Sciences, University of Manchester, UK, based on available data.

Myelosuppression fears remain, other toxicities largely manageable

The side-effect profiles for niraparib, rucaparib and Lynparza are quite similar barring a few factors like liver enzyme elevations that was seen with rucaparib, said Penson. Transient elevation of liver enzymes is generally tolerable, noted D'Andrea, adding side effects like leukemia would be considered as bad toxicities.

If there is no OS survival advantage, it is important to at least offer an improvement in QOL, said Saloustrous.

While myelodysplasia has been seen in some adjuvant studies, in generally PARP inhibitors are

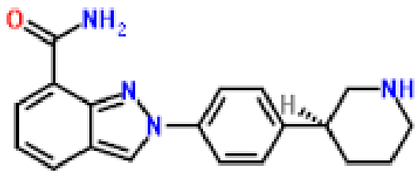


well tolerated, agreed Saloustrous. The important issue with using a PARP as maintenance therapy is that it does not negatively impact subsequent treatments, added Edmondson.

The risk of secondary malignancies is also a major one, said Saloustrous. This news service reported on May 4 that physicians highlighted the risks for PARP-inhibitor treatment to possibly lead to resistance to platinum-based therapies and secondary malignancies.

Companion diagnostic, differences in HRD companion diagnostic still unclear

The understanding that BRCA mutations are not necessary or sufficient for sensitivity to PARP inhibitors was an important one, said D'Andrea. While Lynparza's approval is for gBRCA patients, Tesaro is working with Myriad Genetics (NASDAQ:MYGN) to utilize its myChoice HRD diagnostic to identify patients with HRD mutations, according to a 20 November 2014 release. Comparatively, Clovis is in collaboration with Foundation Medicine (NASDAQ:FMI) aimed at identifying LOH.



Clovis' strategy has generated interest among physicians, this publication reported on 12 May.

HRD is a fairly binomial phenomenon, so a test would be also be binary, said Edmondson. Using HRD, though, is not unique anymore, said Slomovitz. Within the laboratory environment, the different companion diagnostics in development do appear to have fairly similar characteristics and it is expected to translate into the clinical setting as well, he added.

There's no clear idea of which approach is better, said D'Andrea. The best test would be a multiplex test that is a combination of looking at the BRCA gene, the HRD test and other DNA repair genes, he noted. Taking multiple factors into account will improve the predictive power of any test, he added.W

Manasi Vaidya
Reporter, New York

Manasi Vaidya has a Masters degree in biotechnology. After a stint in a research lab, she spent two years as correspondent in India for BioSpectrum, a publication focused on the Asian biotechnology industry. She then moved to the United States to pursue a Masters degree in Science, Health and Environmental Reporting at New York University. Manasi has reported primarily on topics that combine health and policy, and her work has appeared in Nature Medicine, Nautilus and Scienceline. Her coverage at BioPharm Insight focuses on cancer.

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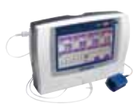
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Biopharmaceutical Report II

AbbVie's Combination Drug for Hepatitis C has Elicited Mixed Expert Opinions

- Success in vitro foreshadows pan-genotypic success
- Six HCV genotypes have unique viral dynamics
- Drug should be bearable for patients even with mild side effects

AbbVie's (NYSE:ABBV) ABT-493/ABT-530 combination drug for hepatitis C has elicited mixed expert opinions on whether earlier positive Phase IIb data in genotypes 1-3 can translate to genotypes 4-6.

Good genotype 3 cohort data and positive pan-genotypic in vitro experiments foreshadow positive data for the remaining genotypes, some experts said. However, others said it is difficult to extrapolate results from one set of genotype to another with each having different clinical manifestations.

The drug's safety profile also appears positive with earlier genotype 1-3 results only reporting one adverse event, they said.

A Phase IIb study of ABT-493/ABT-530 against genotypes 1, 4, 5 and 6 with or without ribavirin (SURVEYOR-I) is due for completion in March 2016 (NCT02243280), ClinicalTrials.gov states. Genotype 1 results are from the SURVEYOR-I trial, whereas the genotype 2 and 3 results are from the SURVEYOR-II trial (NCT02243293), recently released abstracts state.

ABT-493 is an HCV NS3/4A inhibitor and ABT-530 is an NS5A inhibitor, the company website states. NS3/4A is a protease that helps in viral polyprotein maturation and evasion of the host's innate antiviral immunity, while NS5A assists in RNA replication.

AbbVie did not respond to request for comment.

Strong uptake prospects in post-autologous transplant, high-risk patients

Genotype 4 to 6 results could mirror genotype 1 to 3 results

Positive efficacy results against HCV genotypes 4-6 could be drawn based on positive genotype 1-3 trial results, said Dr Brian Conway, medical director, Vancouver Infectious Disease Centre, Canada.

AbbVie recently released three abstracts covering the ABT combo drug efficacy/safety against genotypes 1-3 in this month's Journal of the American Association of the Study of Liver Diseases ahead of the Liver Meeting in San Francisco in November. The abstracts showed 98-100% of 79 patients in the genotype 1 cohort had no detectable HCV after four weeks (SVR4). Between 96-100% of the genotype 2 cohort (75 patients) and 93-96% of the genotype 3 cohort (120 patients) also had SVR4.

The ABT combo drug is envisaged as a once-daily treatment without ribavirin to be taken in less than 12 weeks, the company website states.

Genotype 3 is currently considered as the HCV treatment "weak spot", meaning current drugs are not as effective against this genotype compared to others, Conway said. So, with high SVR4 demonstrated in genotype 3, SV4 results in genotypes 4-6 would likely be even better because they are less complicated to treat, he said.

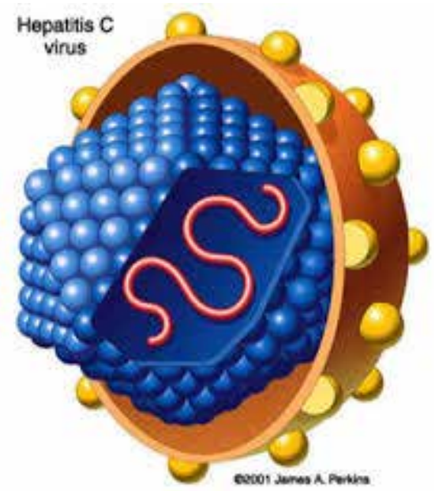
Genotype 3 is the toughest genotype to beat because patients have faster rates of fibrosis progression, steatosis and hepatocellular carcinoma and these patients are generally treated for longer, explained Michael Smith, assistant professor of clinical pharmacy at the University of the Sciences, Philadelphia, Pennsylvania.

In the genotype 3 cohort, there was also only one patient with virologic failure, which is a medical advance considering much higher failure rates are usually observed with this genotype, Conway said. However, more data is needed to see the context of this result, he added.

Based on some data coming out of Egypt-based clinical studies, genotype 4 SVR rates could be tantamount to genotype 1 data, agreed Dr Geoffrey Dusheiko, medicine emeritus professor University College London and Royal Free Hospital in London, England and Abdel-Rahamn Zekri, molecular virology professor, Cairo University, Egypt.

Another reason for optimism would be positive in vitro efficacy results of ABT-493 and ABT-530, Conway added. Posters presented at the Retroviruses and Opportunistic Infections Conference on March 2014 showed the ABT drugs have potent and similar activity against genotypes 1-6, with ABT-493 showing substantially improved in vitro birological profile compared to earlier generation NS3/4A protease inhibitors.

However, Smith argued there are insufficient studies to show results from one genotype can be used to predict results in another genotype. For example, genotype 4 has relatively little data because it is mostly seen in sub-Saharan Africa



Targeted population small, usually does not receive treatment

and Egypt, while most trials are staged in the US and Europe, where genotype 1 is mostly investigated, he said. When the genomes of all six HCV genotypes were mapped by academics, it was discovered they are distant from each other after different evolutions, Dusheiko noted. This means that the six HCV genotypes have unique viral dynamics, treatment response rates and disease progression, he said.

All six genotypes may cause liver cirrhosis, but as all six have different clinical manifestations and in the past required different treatment regimens, Dusheiko said. Dr Jose Debes, gastroenterologist Veterans Affairs Medical Centre, Minneapolis, Minnesota, agreed that extrapolating data from one genotype to another is unfounded because each is unique.

Safety appears positive

The ABT combo drug's safety profile against genotypes 4-6 appears positive, experts agreed, with only one recorded adverse event (AE) in the trials covering genotypes 1-3. One patient in the genotype 3 cohort had to discontinue with the treatment because of abdominal pain and heat sensation, one of the abstracts states.

This specific AE seems ABT-related because this issue has never been reported with ribavirin before, Smith said. However, one patient discontinuing is not really a concern as patients have varying levels of tolerance, he said. It would be worrisome if at least 10% of patients complained or discontinued the drug, he said.

Sometimes abdominal pain and heat sensation can be felt even in placebo drugs, said Debes. Considering the positive response rates, and as long as the AEs are not life-threatening, the drug should be bearable for most patients, he added. Considering the drug is only used for three months to eliminate HCV, patients wouldn't mind some minimal discomfort for long-term benefit, he said.

Most direct-acting antivirals (DAAs) (like the ABT combo drug) are much improved in terms of safety compared with previously used drugs against HCV, Smith said. Ribavirin, for example, which is sometimes used alongside DAAs to improve patient response rates, can cause anaemia, Debes said. Patients only receiving DAAs get generalised nonspecific side effects that vary from drug to drug, he added.

There was one treatment-naïve genotype 1 patient who had post-treatment relapse at week 4, one of the recently released abstracts states. Relapses and virologic failure are usually due to a patient's noncompliance, Smith and Eric Gowans, senior research fellow University of Adelaide, Australia, agreed.

A relapse caused by HCV mutation is unlikely because mutations only happen in treated patients, Gowans said. Because the ABT combo is potent, it also makes mutations the less likely reason for the relapse, Smith added.

AbbVie has a market cap of USD 93bn. W

Reynald Castaneda
Reporter, London

Before moving to London, Reynald was a journalist for healthcare newspaper New Zealand Doctor, covering primary care health politics and medical research. He has a BSc in Biological Sciences from the University of Auckland and a postgraduate diploma in journalism from AUT University. Prior to venturing into journalism, Reynald worked as a laboratory technician for Massey University's Institute of Molecular Biosciences.

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Biopharmaceutical Report III

Controlling Drug Prices

COMMENTARY

Goodwill Hunting

Martin Shkreli and Hillary Clinton last week provided the flint and steel that ignited a dry tinderbox of well-worn ideas about controlling drug prices.

Like all wildfires, the furor flared in the blink of an eye, even by the standards of today's hyperkinetic, Twitter-driven news cycle. Shkreli and his Turing Pharmaceuticals AG were called to account by The New York Times on Sunday for increasing the price of Daraprim pyrimethamine by more than fiftyfold. Clinton rushed in on Monday to fan the flames with a populist crusader's call for reforms, which she issued on Tuesday.

By week's end, Turing had been drummed out of BIO. But not before $145 billion, or 10% of the market value of BioCentury's biotech universe, was wiped out on Wall Street (see "Loose Lips").

While throwing Shkreli and Turing overboard was the obvious thing to do in this fire drill, there's actually little the industry can do collectively to douse the remaining embers.

The price control fires will keep flaring up because they are such easy political pickings, especially as the election season wears on. BIO and PhRMA probably will find ways to lower the heat temporarily because they command seasoned inside-the-Beltway skills. But in the end, it's up to each biopharma company, acting alone, to build goodwill with the public while juggling the apparently conflicting interests of shareholders and patients.

The path forward will be hard, but BioCentury has been pointing out the obvious for years.

Each company's cost structure must be reformed to create headroom for creativity on pricing.

Commercial players have to get serious — quickly — about experimenting with new pricing and access models, coupled to broader approaches for adding patient value.

And R&D players as well as commercial companies have to go beyond platitudes and involve patients in identifying priorities for development of drugs that the patients will want both public and private payers to pay for.

These steps will not usher in an era of peace and harmony for the biopharmaceutical industry, but they are the best responses to the political and economic realities of healthcare.

IT WASN'T ME

Clinton teased her drug pricing policy announcement by tweeting on Monday: "Price gouging like this in the specialty drug market is outrageous," and linking to The Times' story reporting that Turing increased the price of Daraprim from $13.50 per pill to $750. The company had acquired U.S. rights to the antiparasitic compound from Impax Laboratories Inc. earlier in September.

By the end of the week, CEO Shkreli had been thoroughly tarred and feathered in social and mainstream media, and both BIO and PhRMA issued statements distancing themselves from Turing. The biotech trade group then proceeded to formally jettison the company from its membership.

The last step was completely necessary as industry leaders must avoid guilt by association with the handful of companies that cynically extort patients and the healthcare system by jacking up prices on ancient drugs that are in short supply.

At the same time, shunning bad actors won't solve the problem. Shkreli is an excellent piñata for politicians and the media, but he isn't their real target. In fact, the public and politicians don't distinguish between the Turings of the world and companies that actually engage in discovery and development. All they look at is what a drug costs. And what they see is five- and six-digit prices, double-digit price increases, and rising co-pays.

In her tweet and in a campaign speech on Tuesday, Clinton tried to conflate eye-popping increases in the price of an old generic drug with the broader, and far more consequential, issue of the pricing of novel drugs that change the course of disease in unprecedented ways.

Clinton accurately called Turing's pricing of Daraprim "price gouging, pure and simple." However, she followed this with a broader attack on the drug industry. "At the same time this is happening, top pharmaceutical companies are receiving billions of dollars in tax relief every single year and earning billions of dollar in profits every year. And many of them spend more money on marketing and advertising than they do on research."

Clinton went on to accuse industry of marketing me-too drugs as breakthroughs: "Too often, so-called "new" drugs are really old drugs that have just been tweaked a little bit, but then they're marketed as breakthrough drugs, and they're sold for high prices."

HILLARYCARE

Readers who weren't born yesterday will recognize that Clinton's proposals for hammering drug prices were in the works long before she or anyone else had heard of Turing.

Her rhetoric likewise will bring back memories of the first years of the Bill Clinton White House in the early 1990s, when Hillary Clinton and her team of acolytes created a healthcare reform plan that inspired Democrats in Congress to propose a national board to impose "price controls on breakthrough drugs."

That first version of Hillarycare cratered, while the nostrums she proposed last week have been pursued unsuccessfully by the Obama administration for years (see "A Brief History").

Nevertheless, given the gift of the "Turing moment," Clinton last week vowed to make drug prices a centerpiece of her campaign. The candidate asserted that most new drugs are "me-toos" and said that if elected, in addition to extracting billions of dollars in rebates from drug companies, she would regulate their operations to ensure that they spend a "sufficient" amount on research.

Fortunately, campaigning is not governing, and by the time the dust settles on the elections next November and a new president and Congress take over in January 2017, few will remember the promises and proposals candidates made in September 2015. And no substantive legislation, and certainly nothing that fundamentally changes the economics of drug development, will be enacted for the remainder of the Obama administration.

This means there is some breathing room, but it doesn't mean the issue will go away on its own.

Clinton's proposals, and the words she used to present them, were propelled by polling and polished by focus groups that have convinced sophisticated campaign operatives that a substantial segment of the voting population will respond favorably to promises to lower their out-of-pocket costs for drugs, and to assertions that drug companies are rapacious.

HARD CHOICES

The headlines, and the inevitability of continued political attacks on drug prices, reinforce the messages BioCentury has been sending in its annual Back to School essays for the last three years.

In 2013, Back to School argued the "drug industry is going to have to come to grips with the reality that the existing pricing paradigm is not sustainable. This is precisely the opposite of the direction companies are pursuing with their focus on Orphan drugs and ever-smaller cancer indications,

A BRIEF HISTORY

Hillary Clinton's plan for lowering prescription drug costs aggregates ideas that have been staples of Democratic drug cost-containment legislation for over a decade.

Sources: BioCentury, Congressional Budget Office, Congressional Record, FDA, Federal Trade Commission, Hillary Clinton campaign

Proposal	Notes
Eliminate tax deductions for DTC advertising	Legislation seeking to eliminate tax deductions for DTC was introduced in 2002. Similar provisions have been included in many subsequent bills, but have not been enacted.
Establish a mandatory FDA preclearance procedure for DTC ads funded through user fees	Congress established a DTC ad user fee program in 2007, but never authorized FDA to collect the funds. The program was canceled in 2008.
Require pharmaceutical companies that benefit from federal support to either invest a "sufficient" amount of their revenue in R&D or pay rebates to support basic research	The proposal does not define "sufficient" but says Clinton would work with business leaders, experts on drug pricing, and consumer advocates to "set new parameters for federal support."
Require health insurance plans to place a monthly limit of $250 on covered out-of-pocket prescription drug costs	Applies only to on-label uses. Seven states have laws that limit annual, monthly or individual out-of-pocket prescription costs.
Fully fund FDA's Office of Generic Drugs to clear out its multiyear generic drug approval backlog	No details provided.
Shorten the biologic exclusivity period from 12 to 7 years	President Obama tried in the Affordable Care Act and has continued to try unsuccessfully to adopt a seven-year exclusivity period.
Prohibit "pay for delay" agreements that allow drug manufacturers to keep generic competition off of the market	Many bills trying to ban the practice have been introduced; none have been enacted.
Allow Americans to import drugs from abroad	A federal law enacted in 2000 allowed importation only if the HHS secretary certified the drugs would be safe and provide economic benefits to consumers. No HHS secretary has done so. Clinton's proposal would make "FDA and other regulatory agencies" responsible for setting standards for safety and quality of imported drugs.
Require drug manufacturers to provide rebates for low-income Medicare enrollees that are equivalent to rebates in the Medicaid program	PhRMA agreed to tens of billions of dollars of rebates and taxes in ACA to avoid rebates on dual eligibles. In 2011, the Congressional Budget Office estimated that such rebates would save the government $120B over 10 years.
Allow Medicare to negotiate drug and biologic prices	The CBO has said CMS could not negotiate better prices than those obtained by Medicare Part D plans.
Build on provisions in ACA that invest in and use private-sector analyses to hold drug companies accountable for justifying their costs and ensure Americans pay drug prices that reflect the improved value new treatments provide	No details provided.

which they expect will continue to be priced at eye-popping levels with eye-popping margins and a steady dose of price increases."

At the time, Back to School also said industry was heading in a direction that was "destructive to both the industry and its investors in the long run by making payer and public backlash even harsher than it already is." BioCentury called for the drug industry to "participate in shaping the system that defines innovation," or face the prospect of payers making decisions based solely on cost.

In 2014, Back to School warned that a backlash against drug pricing in the U.S. meant the "last bastion of free pricing is crumbling" and argued that "biotech and pharma had better start experimenting with new pricing models based on value for money while they still have the chance."

This year, Back to School argued for much deeper industry engagement with patients, noting that they can "help define the value of medical interventions for payers, and for other patients, in ways that are far more convincing than anything drug developers can say."

Patient-driven drug development, BioCentury argued, is "both inevitable and essential to improving product offerings, shortening development times and achieving product approval and reimbursement."

These necessary changes will be difficult, and some will be painful, but there will be no way around the fact that drug companies need to adapt to a world in which they have less pricing power.

It means drug companies will have to dig far more deeply to reform their cost structures to shore up profits and dividends as prices flatten, discounts rise and the cost of providing the clinical outcomes beyond simply distributing pills and vials goes up.

They also will have to reset the expectations of shareholders who have come to expect profits that are not just above average, but far above average.

The resulting short-term reduction in valuations, and a turnover in shareholders who want above-average dividends rather than innovation, may be the price pharma companies have to pay to make the kinds of changes that are necessary to ensure their long-term viability.

The key point is that goodwill is created one company at a time, not by trade groups inside Washington.

This is not a PR exercise. No amount of investment by trade associations in communications or lobbying will get the job done. Indeed, PhRMA and BIO have spent decades trying to improve the public's perception about the industry, with little if anything to show for their efforts.

The trade groups have had important lobbying successes, preventing Congress from afflicting the industry with countless plagues. But the rising influence of populists in both parties will make it increasingly more arduous for them to kill legislation.

The only thing that can work is for each drug company to show through pricing and access decisions that it is serving the public interest.

Some promising first steps have been made along these lines. For example, Novartis AG is working on a performance-based pricing model for Entresto sacubitril/valsartan under which the pharma would have to earn an increase in price from deep discounts offered at launch by showing the new heart failure drug produces downstream healthcare savings, such as by reducing hospitalizations.

In collaboration with drug companies — and, in fact, in response to pharma interest in pricing experiments — Express Scripts Holding Co. will pilot an indication-based pricing scheme that involves variable reimbursement rates

Remember Ira Magaziner, head of President Bill Clinton and Hillary Clinton's healthcare reform project?
He's vice chairman and CEO of the Clinton Health Access Initiative, part of the Clinton Foundation. It's a safe bet that he'd be back in the White House if Hillary Clinton were elected.
SOURCE: JOI (OWN WORK) [GFDL OR CC BY 3.0], VIA WIKIMEDIA COMMONS

for cancer drugs that are commensurate with the degree of bene t the drugs provide in different cancers.

If more R&D companies partner with patients and payers to prioritize clinical needs, define and demonstrate value, and agree on plans that ensure access to medicines, then these constituents will have a stake in preventing the most ruinous political policies that would be imposed if the current trajectory is not modified.

Unsigned Commentary represents BioCentury's Editorial viewpoint.

COMPANIES AND INSTITUTIONS MENTIONED

Biotechnology Industry Organization (BIO), Washington, D.C.
Express Scripts Holding Co. (NASDAQ:ESRX), St. Louis, Mo.
Impax Laboratories Inc. (NASDAQ:IPXL), Hayward, Calif.
Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland
Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C. Turing Pharmaceuticals AG, New York, N.Y.

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WHY "NEW STANDARD" READY-TO-USE

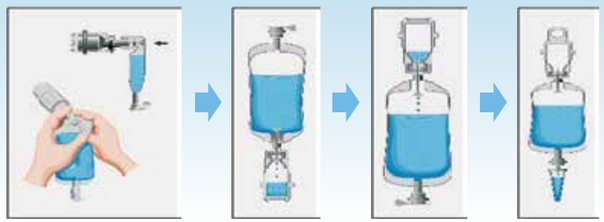
INNOVATIONS

+

ADVANTAGES

UK INJECTION KIT(FULL KIT)

State of the art
UK Injection Kit



CONNECT TO VEIN DRIPPING SYSTEM

- ✓CLOSED SYSTEM APPLICABLE FOR USP CHAPTER <797>
- ✓REDUCE THE RISK OF MICROBIAL CONTAMINATION
- ✓FASTER PREPARATION TIME WITH READY TO MIX SYSTEM
- ✓REDUCE THE NEEDLE INJURY AND ANTIBIOTIC ALLERGY OF PRACTITIONER
- ✓WIDE RANGE OF ANTIBIOTIC PRODUCT PORTFOLIO
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FOLLOW THE JOURNEY OF VIREAD

#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.

300mg tablets® Viread® 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 DETECTED AT YEAR 1 THROUGH YEAR 8

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]

0%

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)

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

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.

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 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)*.

Brief Summary (Cont'd)

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

International conference and exhibition on Cosmetic Dermatology and Hair Care
December 07-08, 2015 Philadelphia, USA

Website: http://cosmeticdermatology.conferenceseries.com
Contact person: haircare@omicsgroup.com

The theme of the conference is, "Expanding the Possible methods and approaches in the field of Cosmetic Dermatology & Hair care". This conference aims at bringing together the professors, researchers, clinicians, educators, program developers, dermatologists, cosmetic dermatologists and hair transplantation surgeons to provide an international forum.

Keystone Symposia : Cell Biology and Immunology of Persistent Infection
January 31–February 4, 2016 Alberta, Canada

Website: http://www.keystonesymposia.org/16A8
Contact person: info@keystonesymposia.org

This meeting is designed to bring together diverse communities of researchers at the cutting edge of their fields to understand whether and how to manipulate persistent infections to prevent disease and enhance health.

Keystone Symposia: Fibrosis: From Basic Mechanisms to Targeted Therapies
February 7–11, 2016 Colorado, USA

Website: http://www.keystonesymposia.org/16Q3
Contact person: info@keystonesymposia.org

Present and discuss the most current and cutting-edge results regarding the mechanisms, signaling pathways, gene regulation, cells and tissues involved in fibrotic diseases and therapeutic approaches currently in development.

MiSS- 16th Annual Minimally Invasive Surgery Symposiums
February 23 - 26, 2016 Las Vega, USA

Website: http://www.miss-cme.org/site/Default.aspx
Contact person: Philip R. Schauer, MD

The 16th Annual Minimally Invasive Surgery Symposium (MISS) will offer compelling lectures, surgical video presentations, and lively discussion and debate by world-renowned experts on advanced laparoscopic techniques for managing metabolic disorders, hernia, foregut and diseases of the colon.

6th World Congress on Cell & Stem Cell Research
February 29-March 02, 2016 Philadelphia, USA

Website: http://stemcell.omicsgroup.com/
Contact person: Haval Shirwan, MD

Stem Cell Research-2016 has the goal to fulfill the prevailing gaps in the transformation of this science of hope, to serve promptly with solutions to all in the need. Stem Cell Research 2016 will have an anticipated participation of 300+ delegates across the world to discuss the conference goal.

6th International Conference and Expo on Proteomics
March 29-31, 2016 Atlanta, USA

Website: http://www.proteomicsconference.com/america/
Contact person: Steven Pelech, MD

World Proteomics 2016 includes central topics on The Discovery of Proteomics, Proteomics with Computational Natural Science, The High-Throughput Technologies, The Trends in Clinical Proteomics, A Scientific Approach of Proteomics, The Developments of Systems Biology, The Machine Learning Technique, Neuro and Nutri Proteomics, Proteomics Case Study and more.

NutriFood 2016- International Conference on Advances in Human Nutrition, Food Science & Technology
June 26-27, 2016 Toronto, Canada

Website: http://www.health3000.org/nutrifood/
Contact person: Bhagya Prabodini

NutriFood2016 will give an opportunity to present your work before a global audience while upgrading your knowledge through greater interaction with experts in the field. Best premier knowledge building event in Human Nutrition and Food Sciences.

Europe

2016 Pharma CI Europe Conference & Exhibition
February 18-19, 2016, PARIS, FRANCE

Website: http://europe.pharmaciconference.com/
Contact person: info@pharmaciconference.com

This is the only event featuring a world-class line up of speakers and panelists offering their unique insights and expertise on the topics you care about most. The Pharma CI Conference & Exhibition is THE INDUSTRY'S GOLD STANDARD for senior level pharma, biotech, and device professionals seeking the latest news and the rare chance to network with all the industry's luminaries.

Eunrope

6th Euro Virology Congress and Expo
March 10-12, 2016 at Madrid,Spain

Website: http://virology.omicsgroup.com/europe/

This conference is focusing on the theme “An Insight on Advances in Virology and Infectious Diseases”. The conference invites participants from all leading universities, research institutions, microbiologists, virologists and diagnostic companies to share their research experiences on all aspects of this rapidly expanding field.

Pharmaceutica 2016:8th International Conference and Exhibition on Pharmaceutics & Novel Drug Delivery Systems
March 07-09, 2016 at Madrid, Spain

Website: http://novel-drugdelivery-systems.pharmaceuticalconferences.com/
Contact person: haircare@omicsgroup.com

Pharmaceutica 2016 conveys recent developments in Novel Drug Delivery Systems (NDDS), advances in drug delivery systems and approaches. A complete knowledge of the relevant therapeutic and physicochemical properties of the drug enables determination of its proper formulation and delivery method.

2016 3rd International Conference on Food Security and Nutrition - ICFSN
23rd to 25th March 2016 Amsterdam, Netherlands

Website: http://www.icfsn.org/
Contact person: Mr Issac Lee

IPCBEE, ISSN: 2010-4618, and all papers will be included in the Engineering Technology Digital Library, and indexed by Ei Geobase(Elsevier), CABI, Ulrich’s Periodicals Directory, EBSCO, CNKI, WorldCat, Google Scholar, Cross ref.

Asia

ISERD - 11th International Conference on Science and Innovative Engineering (ICSIE)
December 6th, 2015 in Shanghai, China

Website: http://www.iserd.co/Conference/China/ICSIE/

ISERD – 11th International Conference on Science and Innovative Engineering (ICSIE) aimed at presenting current research being carried out in that area. This conference provides opportunities for the delegates to exchange new ideas and application experiences face to face, to establish business or research relations and to find global partners for future collaboration.

Asia

International Conference of Biomolecular Engineering ICBE
January 5-7, 2016 Singapore, Singapore

Website: http://www.aiche.org/sbe/conferences/international-conference-biomolecular-engineering-icbe/2016
Contact person: bio@aiche.org

CBE brings together researchers who are using quantitative approaches to advance the understanding and application of molecular biology. These scientists, engineers, and professionals are contributing to the development of analytical, molecular, high-throughput, and therapeutic strategies that are directly relevant to public health and energy related issues.

6th Emirates Otorhinolaryngology Audiology and Communication Disorders Congress
January 13–15, 2016 Dubai, United Arab Emirates

Website: http://www.emiratesrhinologyandotology.ae/
Contact person: eroc@mci-group.com

The 6th Emirates Rhinology & Otology Conference will gather a world-class panel of expert speakers, from international and regional communities. It will provide a platform to share experiences by discussing breakthroughs in various specialist fields - prerequisite to successfully assess and expand the current practices carried out in the field.

Third International Conference on Global Public Health 2015
December 10-11, 2015 Colombo, Western, Sri Lanka

Website: http://www.health3000.org
Contact person: Prabhath Patabendi

Global Public Health 2015 is an interactive platform to connect and reconnect colleagues around the world. Meet 2012, 2014 participants as well as new participants in our conferences. GPH 2015 conference is the premier knowledge building event in GPH.

2016 7th International Conference on Food Engineering and Biotechnology - ICFEB
March 12-14, 2016 Singapore

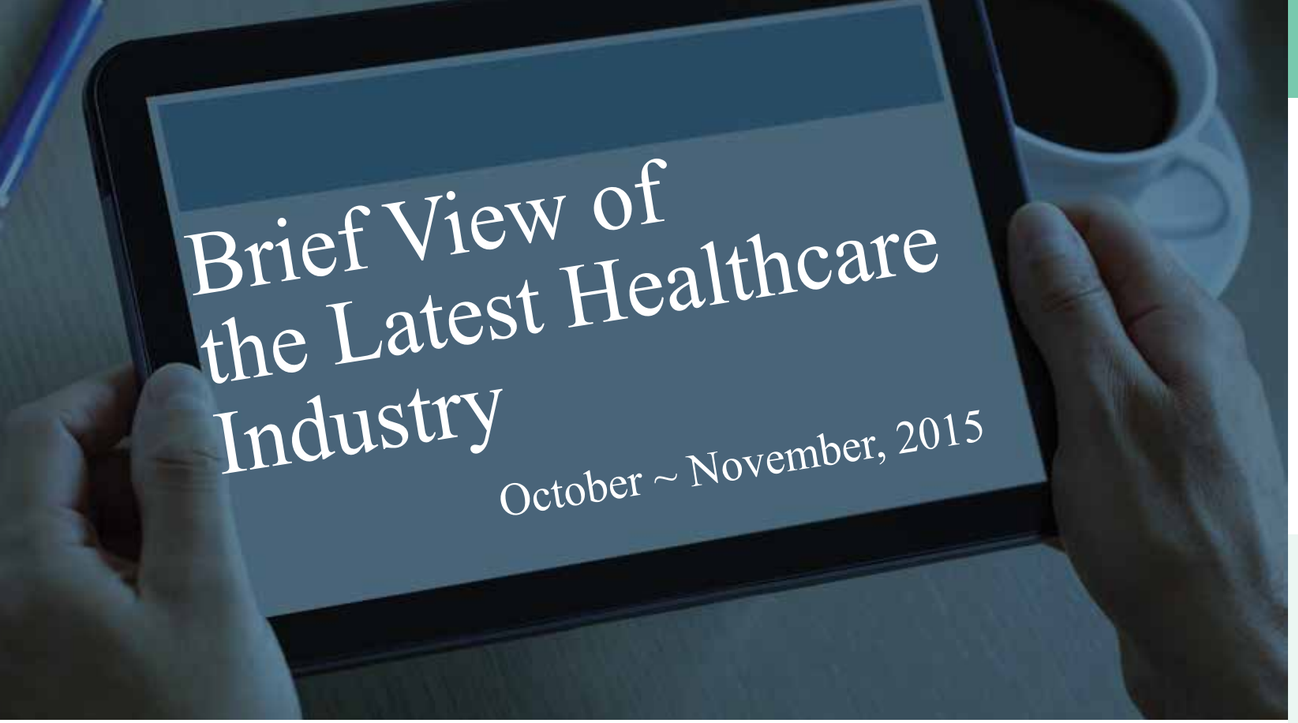
Website: http://www.icfeb.org/
Contact person: Ms Lydia Liu

International Journal of Life Sciences Biotechnology and Pharma Research (ISSN:2250-3137), which will be indexed by Embase (Under elsevier), ProQuest, Google Scholar, Chemical Abstracts Services (CAS), Indian Science, ICMJE, HINARI, and NYU.

PHC 2016 - Public Health Conference 2016
July 11-13, 2016 Kuching, Sarawak, Malaysia

Website: http://www.publichealth-conference.org
Contact person: Vladimir Mladjenovic

PHC 2016 is a forum, discussion and networking place for academics, researchers, professionals, administrators, educational leaders, policy makers, industry representatives, students, and others interested in the topics related to medicine and health.



October

1. FDA Approves Two New Drug Treatments for Diabetes Mellitus

According to the Centers for Disease Control and Prevention, approximately 21 million people in the United States have been diagnosed with diabetes. Over time, diabetes increases the risk of serious health complications, including heart disease, blindness, nerve and kidney damage. Improvement in blood sugar control can reduce the risk of some of these long-term complications. The U.S. Food and Drug Administration has approved Tresiba and Ryzodeg 70/30 to improve blood sugar (glucose) control in adults with diabetes mellitus. Tresiba is a long-acting insulin analog indicated to improve glycemic control in adults with type 1 and 2 diabetes mellitus. Ryzodeg 70/30 is a mixture of insulin degludec, a long-acting insulin analog, and insulin aspart, a rapid-acting human insulin analog. It is indicated to improve glycemic control in adults with diabetes mellitus.

http://www.medicalnewstoday.com/releases/300212.php

2. Blood Test Could Replace Biopsy for Cancer Diagnosis

A simple blood test could be on the way to replacing the biopsy as the gold standard for detecting cancer, saving lives and money, according to researchers in the UK. The new treatment was presented at the annual World Conference on Lung Cancer in Colorado by Eric Lim, consultant thoracic surgeon at Royal Brompton & Harefield National Health Service (NHS) Foundation Trust. The new study, carried out at Imperial College London, involved 223 patients with known or suspected primary or secondary lung cancer who were about to undergo surgery. In nearly 70% of cases, the blood test was accurate in predicting the presence of cancer cells.

http://www.medicalnewstoday.com/articles/299307.php

November

3. US FDA Sends Letter to DNA4Life Over Consumer Gene Tests

The U.S. Food and Drug Administration sent a warning letter to privately held gene testing company DNA4Life over its sale of an unapproved direct-to-consumer gene test to predict drug response. In its letter, the agency said it was unable to identify any FDA clearance for the company's test. The letter follows 23andMe's limited relaunch last month of a series of direct-to-consumer tests after the agency ordered the tests off the market. DNA4Life told Reuters in an earlier interview that it did not believe it needed FDA approval to sell its test.

http://www.nytimes.com/reuters/2015/11/09/us/09reuters-usa-genetics-dna4life-fda.html

4. Obama Administration Sets Stage for a Debate on Drug Costs

The Obama administration set the stage for a national debate on the rising cost of prescription drugs. Saying that too many people are struggling to pay for their medications, Health and Human Services Secretary Sylvia Burwell opened a daylong forum that presented a range of perspectives, from the pharmaceutical industry to a cancer patient with $270,000 in bills for just one drug. President Barack Obama has called for giving Medicare legal authority to negotiate prices for high-cost "specialty drugs," a small percentage of innovative medications that accounts for more than one-third of spending.

http://www.nytimes.com/aponline/2015/11/20/us/politics/ap-us-drug-costs.html?_r=0

5. U.S Funds Optimistic About Allergan Piled in Before Pfizer Bid

Several large U.S. funds that boosted their stakes in Allergan Plc in recent months appear to be optimistic about the company's growth prospects, even before Pfizer's reported $150 billion takeover bid for the botox maker. Pfizer Inc is negotiating to buy Allergan, which also makes dry eye treatments, for $370 to $380 per share, a person familiar with the discussions said, compared to its current traded value of around $301. There is some dissatisfaction, however, with that price range, according to a poll by Sanford C. Bernstein research. Its poll of 87 investors showed that 54 percent wanted $390 to $400 a share, but 36 percent were satisfied with the lower reported price range.

http://www.nytimes.com/reuters/2015/11/20/business/20reuters-allergan-pfizer-investors.html

6. Why New Tax Inversion Rules Won't Stop Pfizer-Allergan Deal

Pfizer's Allergan inversion deal may be too big for even the U.S. government to stop. The U.S. Treasury Department issued new rules to limit tax inversion deals to stop U.S. companies from cheaply picking up small companies just for tax purposes. An inversion takes place when a U.S. company buys a smaller, foreign rival and reincorporates overseas in order to avoid U.S. taxes.

The new rules include provisions against "asset stuffing" and "cherry picking." Though, neither of these rules will affect the Pfizer deal because the drug maker has agreed to pay up for rival Allergan,
making the deal a so-called super inversion. Pfizer-Allergan split goes beyond 60-40 which is beyond inversion rule's established bars. Pfizer is reportedly going to pay $150 billion for Allergan.

That's 22% higher than where the company is trading right now. And Allergan's shares have already risen nearly 25% on the potential Pfizer deal, to around $310. Pfizer has a market cap of around $200 billion. So the combined company will be worth roughly $350 billion. The government can't stop companies from paying up for tax inversions, even if it would be better for shareholders if it could.

http://fortune.com/2015/11/20/why-new-tax-inversion-rules-wont-stop-pfizer-allergan-deal/

November

7. Sanofi, Hanmi Seal Diabetes License Deal for up to $4.2 Billion

Sanofi has signed a license deal with Hanmi Pharmaceutical to develop experimental, long-acting diabetes treatments, the French drugmaker said on Thursday, in a move to revive its diabetes division. South Korea-based Hanmi will receive an upfront payment of 400 million euros ($434 million) and is eligible for up to 3.5 billion euros in development, registration and sales milestones, as well as double-digit royalties on net sales. In return Sanofi will get an exclusive worldwide license to develop and commercialize Hanmi's so-called GLP-1 diabetes treatments. Hanmi will retain an exclusive option to co-commercialize the products in Korea and China.

http://www.reuters.com/article/2015/11/05/us-sanofi-hanmi-diabetes-idUSKCN0SU0R120151105#DqvPQ1LuJSETZvI2.97

8. Hanmi, Janssen Launch Up-to-$915M+ Diabetes/Obesity Alliance

Hanmi Pharmaceutical said it will partner with Johnson & Johnson's Janssen Pharmaceuticals to develop the Korean pharma's Phase II-ready diabetes and obesity candidate HM12525A (LAPSGLP/GCG) and other oxyntomodulin-based therapies. The collaboration could generate up to $915 million for Hanmi. Janssen agreed to obtain exclusive worldwide rights—except for Korea and China—to develop and commercialize HM12525A. In return, Janssen agreed to pay Hanmi $105 million upfront, and up to $810 million in payments tied to achieving potential clinical development, regulatory, and sales milestones. Hanmi would also be eligible for tiered double-digit royalty payments if HM12525A is successfully commercialized.

http://www.genengnews.com/gen-news-highlights/hanmi-janssen-launch-up-to-915m-diabetes-obesity-alliance/81251950/

9. AstraZeneca, Sanofi Agree to Share Proprietary Compounds

AstraZeneca PLC and Sanofi SA have agreed to share thousands of their proprietary chemical compounds with each other, an unusual deal that shows the creative lengths to which pharmaceutical companies will go to pursue new drugs. The deal involves each company giving the other free access to 210,000 usually closely guarded compounds. Each company can develop any of the shared compounds without any financial obligation to the other. It is rare for companies to share their so-called compound libraries with outsiders, because these are the starting point for traditional drug development and are expensive to build up. But Mene Pangalos, head of innovative medicines development at London-based AstraZeneca, said he didn't see "any risks" in sharing around a 10th of the company's library with Paris-based Sanofi, even though the pair directly competes in several disease areas.

http://www.wsj.com/articles/astrazeneca-sanofi-agree-to-share-proprietary-compounds-1447977780

10. Doctors' Proposed Ban of Drug Ads Goes After Top Magazine Ad Category

Pharmaceutical companies spent $4.5 billion on advertising prescription medications in the U.S. in 2014, up 18% from the prior year, according to data from WPP research firm Kantar Media. The American Medical Association has called for a ban of direct-to-consumer advertising of prescription drugs, a major source of ad revenue for print magazines. The AMA, a professional organization of doctors in the U.S., said it has adopted a new policy supporting the ban of such ads and for greater transparency in prescription drug prices and costs. Legislation would need to be passed by Congress to ban direct-to-consumer advertising of drugs and the issue would likely raise questions about potential First Amendment violations. Efforts to sharply restrict direct-to-consumer advertising of prescription drugs have been defeated by Congress in the past.

http://www.wsj.com/articles/doctors-proposed-ban-of-drug-ads-goes-after-top-magazine-ad-category-1447885280

November

11. Coty to Buy Hypermarcas Beauty Business for About $1 Billion

Coty Inc. agreed to buy the personal-care and beauty division of Brazil's Hypermarcas SA for about $1 billion in cash, turning again to acquisitions to expand its burgeoning cosmetics line. The Hypermarcas beauty business generated $253.5 million in revenue last year with brands such as Risqué nail polish and Paixão skin-care products. The move follows an agreement in July to acquire more than 40 Procter & Gamble Co. beauty brands, a $12.5 billion deal that's poised to turn Coty into one of the world's largest cosmetics companies The Hypermarcas deal gives Coty a platform to sell its existing lineup in Brazil, as well as the products it's getting from P&G. The Hypermarcas transaction is slated to close by the end of March, while completion of the P&G deal is expected in the second half of 2016.

http://www.bloomberg.com/news/articles/2015-11-02/coty-to-acquire-hypermarcas-beauty-business-for-about-1-billion

12. Dangerous Chemicals in Cosmetics Spur Action by Lawmakers

Cosmetics and skin care products are largely unregulated. Today's products are made with chemicals like formaldehyde -- used in products from nail polish to some chemical hair straighteners - which is known to cause cancer. Other commonly used cosmetic preservatives include propylparaben and lead acetate, used in hair dye. Under the proposed law, the FDA would test whether those chemicals are being used at safe levels. If not, they can force a recall. The biggest offenders are hair products, especially straighteners, and newer nail polishes that last more than a week - all largely unregulated. That's not the story in other countries. The European Union bans more than 1,000 chemicals from personal care products. Of those, the U.S. bans 11. Dermatologist Dr. Elizabeth Tanzi was on Capitol Hill to urge Congress to pass the tougher new legislation.

http://www.cbsnews.com/news/new-legislation-proposes-greater-fda-oversight-of-chemicals-used-in-beauty-skin-products/

13. FDA Approves Cotellic as Part of Combination Treatment for Advanced Melanoma

The U.S. Food and Drug Administration has approved Cotellic, a drug produced by Swiss biotech company Roche, for use in combination with the vemurafenib medication as a treatment for advanced melanoma. The drugs are intended to target the illness after it has spread to other parts of the body or can't be removed by surgery. The FDA said the safety and efficacy of Cotellic in combination with vemurafenib were shown in a clinical study of 495 patients with previously untreated, advanced melanoma that demonstrate the BRAF V600 mutation.

http://www.wsj.com/articles/fda-approves-roches-cotellic-treatment-for-melanoma-1447182496

15. World's Top Innovator South Korea Dominates Asian Stock Winners

South Korea, which topped the Bloomberg Innovation Index in January, is now dominating Asian stock markets with seven of the 10 best performers this year. In the Bloomberg Innovation Index for 2015, South Korea ranked No. 1 in measures of research and development, patents and post-secondary education and fourth in hi-tech companies, while scoring highly in both manufacturing and research personnel. Hanmi Science Co. and affiliate Hanmi Pharm Co. soared 919 percent and 681 percent each after clinching deals to sell lung cancer and diabetes treatments overseas. Amorepacific Corp. climbed 107 percent as its Air Cushion foundation cream won positive reviews, driving a 51 percent jump in its net profit in the nine months through September. Celltrion Inc., which developed an arthritis medicine, more than doubled.

http://www.bloomberg.com/news/articles/2015-11-11/world-s-top-innovator-south-korea-dominates-asian-stock-winners

IT WAS HARD TO TELL THE McCARTHY TWINS APART. THEY EVEN HAD THE SAME CANCER.

Fortunately, they also had the same hospital: the University of Chicago Medicine. Kelly McCarthy was eight months pregnant when she was diagnosed with stage IIB breast cancer. After her son was born, she underwent chemotherapy, radiation, and surgery to remove her right breast. Just four months later, her identical twin Kristen was diagnosed with stage 0 breast cancer, requiring a double mastectomy followed by reconstructive surgery. Later, when Kelly underwent a second mastectomy and also required reconstruction, **Dr. David Song** transplanted some of Kristen's skin and tissue to create one of Kelly's new breasts. Which is why these twins will tell you the same thing: There's no other medical center like the University of Chicago Medicine. For more information, contact James Bae, Regional Manager of International Programs at youngjoo.bae@uchospitals.edu or call +1-224-315-3948.

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