

O Sun God, Savitr!
Thou dazzling fount of life-persuasive light!
Sublimest mystery speeding from afar!
Swift became that burst too potent on the sight!
This radiant type of strength and youth!
Glowing eternally!



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May the golden-eyed Savitar, come hither!
Shining forth he rises from the lap of the dawn!
Praised by singers, my God Savitar!
Stepped forth and never missed his place!
He steps forth the splendor of the sky the wide!
Seeing, far-shining, the shining wanderer!
- Rig Veda, vii, 65

He alone shines!
All luminaries get illuminated by His Illumination!
The whole Universe is enlightened by His light!
- Kathopanisad

The Telangana Science Journal

Health and Nutrition

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Home	The Foundation	Management	The Andhra Journal of Industrial News	The Telangana Science Journal	Mana Sanskriti (Our Culture)
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Issue 241

Chief Editor: డాక్టర్ శ్రీనివాసరావు వేపచేదు | डॉक्टर श्रीनिवासरावु वेपचेदु | Dr. Sreenivasarao Vepachedu¹

DRUG DISCOVERY



“Doctors have always recognized that every patient is unique, and doctors have always tried to tailor their treatments as best they can to individuals. You can match a blood transfusion to a blood type — that was an important discovery. What if matching a cancer cure to our genetic code was just as easy, just as standard? What if figuring out the right dose of medicine was as simple as taking our temperature?” - President Barak Hussain Obama, January 30, 2015¹

One hundred years ago, the pharmaceutical industry provided a home for a highly successful alliance between chemistry and pharmacology, involving isolation and purification of the active ingredients of medicinal plants, using coal-tar based aromatic and aliphatic building blocks that became the toolkit of medicinal chemistry. Chemistry, pharmacology, microbiology, and biochemistry shaped the drug discovery and brought it to a new level complexity involving biochemical mechanism of action.

Today's drug discovery's complexity is at a new level beyond the traditional pharmaceutical industry's chemistry and pharmacology. Target-oriented synthesis of small molecules² using modern methods of stereoselective organic synthesis and parallel and combinatorial approaches have increased the efficiency of synthesis of small molecules. The advent of genomic sciences, rapid DNA sequencing, cell-based assays, and automated high-throughput screening (HTS) has led to about 5 million to about 50 million compounds screened at a given pharmaceutical company by the middle of the 1990s, without any commensurate increase in productivity measured by the number of new small molecule drug compounds entering the market place³. The library size is not enough to succeed. Another factor that plays an important role is molecular structural and functional diversity of the library, the creation of which involves Diversity Oriented Synthesis (DOS) with four principal components: Building Block Diversity, Functional Group Diversity, Stereochemical Diversity, and Skeletal (Scaffold) Diversity⁴, and Fragment-Based Drug Discovery (FBDD), or a combination of DOS and FBDD⁵.

Molecular biology added another layer of complexity to the drug discovery involving therapeutically effective large molecules such as proteins and spawned a new drug industry called biotech or biologics. Biological products include a wide range of products⁶ such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge

Issue 241	5118 కలి కాలము/Kali Era 2074 విక్రమార్క కాలము/Vikramarka Era 1938 శాలివాహన కాలము/Salivahana Era స్వస్తి శ్రీ హేవిళంబి నామ సంవత్సరము/स्वस्ति श्री हेविलम्बी नाम संवत्सर/Swasti Sri Hevilambi Year మాఘమాసము/MAGHA Month Published online 1 FEBRUARY 2018
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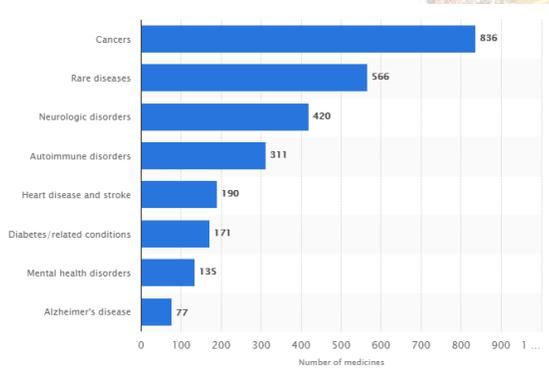
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Home	The Foundation	Management	The Andhra Journal of Industrial News	The Telangana Science Journal	Mana Sanskriti (Our Culture)
Vegetarian Links	Disclaimer	Solicitation	Contact	VPC	Vedah-net

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technologies. Gene-based and cellular biologics may be used to treat a variety of medical conditions for which no other treatments are available. The Biologics Control Act, passed in 1902, was the first law aimed at ensuring the safety of some of the earliest biologics such as vaccines in the US, to manage the danger posed by biological products produced in animals and their administration by injection, instigated by the 1901 death of thirteen children in St. Louis after receiving diphtheria antitoxin contaminated with tetanus spores⁷.



By the turn of the millennium, there were 59 such biologics or biotech drugs, mostly recombinant proteins and monoclonal antibodies⁸. By 2016, biologics had surged to make up 25 percent of the total pharmaceutical market, bringing in US\$ 232 billion⁹. There were 836 biologic medicines in development for cancer and cancer-related conditions alone, and a total of 2706, as of June 2017¹⁰. However, there were about 200 biologics for neurological disorders such as Alzheimer's Disease (about 77).

The US Food and Drug Administration has approved new protein-based biologics for the treatment of cancer, Lupus, Crohn's disease, rheumatoid arthritis, multiple sclerosis, kidney failure, asthma and high cholesterol. However, the steep prices of biologic drugs are not sustainable to many patients. Amgen's T-VEC is estimated to cost an average of \$65,000 per patient. Brineura, a biweekly enzyme replacement therapy produced by BioMarin Pharmaceutical, costs \$27,000 per injection, or more than \$700,000 for a full year's treatment¹¹.

The average daily cost of a biologic in the United States is \$45 compared with only \$2 for chemical (small-molecule) drugs. Approximately 95% of all drug projects never make it to market, only 1 in 10 approved drugs become a commercial success, the average time to obtain approval to market a drug is 13.5 years, and the average cost of developing a new biotechnology drug as of December 2012 was estimated to be approximately \$1.9 billion¹². The estimated average pre-tax industry cost per new prescription drug approval is about \$ 2.6 billion¹³.



Recently, Pfizer decided to close its neuroscience discovery and early development programs. It is the latest large drug maker to stop developing drugs for central nervous system disorders¹⁴. Neurological disorders comprise more than 600 conditions that affect the nervous system. Together, these disorders

Issue 241	5118 కలి కాలము/Kali Era 2074 విక్రమార్క కాలము/Vikramarka Era 1938 శాలివాహన కాలము/Salivahana Era స్వాస్తి శ్రీ హేవిళంబి నామ సంవత్సరము/स्वस्ति श्री हेविलम्बी नाम संवत्सर/Swasti Sri Hevilambi Year మాఘమాసము/MAGHA Month Published online 1 FEBRUARY 2018
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Home	The Foundation	Management	The Andhra Journal of Industrial News	The Telangana Science Journal	Mana Sanskriti (Our Culture)
Vegetarian Links	Disclaimer	Solicitation	Contact	VPC	Vedah-net

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impact an estimated 50 million Americans every year. According to a study from the Bill and Melinda Gates Foundation, neurological disorders represent eight percent of the global health burden. Central Nervous System (CNS) disorders bear an economic burden of more than \$2 trillion in the US and EU. However, chances of a drug for Alzheimer's Disease reaching the market are nearly 50% lower, and development costs are 30% higher than those of its cardiovascular counterpart¹⁵.

Since 2011, GSK, AstraZeneca and Novartis have announced closures of neuroscience divisions globally. Johnson & Johnson, Bayer, GlaxoSmithKline, and Gilead Sciences list no Alzheimer's drugs in development. Sanofi, Janssen, and Merck have begun to significantly downsize CNS operations due to costs running into billions more than any other therapeutic area, with a 45% higher chance of failure than drugs targeting other disorders. In 2012, Pfizer's Bapineuzumab and Eli Lilly's Solanezumab failed in the biggest Phase III studies of the year. Baxter's Alzheimer's lead Gammagard failed Phase III in 2013. Merck's beta secretase-1 (BASE) inhibitor MK-8931 failed in 2017 in protocol 017, also known as the EPOCH study, as there was virtually no chance of finding a positive clinical effect¹⁶. On February 1, 2018, Roche announced it was dumping a host of early- and late-stage candidates- RG7417 for geographic atrophy, RG7986 for refractory B-cell non-Hodgkin's lymphoma, RG6047 for metastatic estrogen receptor-positive and HER2-negative breast cancer, RG7604 for uterine carcinoma, RG7203 for the treatment of schizophrenia, etc¹⁷.

In 2015, biopharmaceutical companies were in the process of developing 420 medicines for neurological disorders¹⁸. Pfizer, the world's third largest pharmaceutical company, had nine drugs in clinical development, including four for Alzheimer's Disease. Over the last 20 years, Pfizer had 99 clinical trials of 24 potential Alzheimer's drugs and had only one approval: Aricept (donepezil hydrochloride). A single human clinical trial may cost 100s of millions of dollars. No wonder, Pfizer decided to close its neuroscience discovery eliminating about 300 jobs. Interestingly, after having cut down neuroscience programs and laid off hundreds of scientists in 2013, Abbvie opened a new 43,000-square-foot Foundational Neuroscience Center (FNC) in Cambridge, Massachusetts in 2016¹⁹, indicating that the interest in a particular field of drug discovery is cyclical²⁰ depending upon the mood of the shareholders²¹.

The pharmaceutical-biotech industry is very competitive and powerful sustained by legal grants of monopoly power to enable originator firms to recoup their R & D costs including patent grants and regulatory market exclusivities. However, unfortunately, keeping the long-term goals in sight that is so crucial to drug discovery and development is lost in the pursuit short-term goals of shareholders watching the stock price²², while short-term grants of monopoly are threatened by short-term goals of patients to get cheaper drugs to extend lives of individuals.

Issue 241	5118 కలి కాలము/Kali Era 2074 విక్రమార్క కాలము/Vikramarka Era 1938 శాలివాహన కాలము/Salivahana Era స్వస్తి శ్రీ హేవిళంబి నామ సంవత్సరము/स्वस्ति श्री हेविलम्बी नाम संवत्सर/Swasti Sri Hevilambi Year మాఘమాసము/MAGHA Month Published online 1 FEBRUARY 2018
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Home	The Foundation	Management	The Andhra Journal of Industrial News	The Telangana Science Journal	Mana Sanskriti (Our Culture)
Vegetarian Links	Disclaimer	Solicitation	Contact	VPC	Vedah-net

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The pharmaceutical industry, facing many such business challenges and to maximize profitability and supplement the existing pipeline, must accelerate new drug development, introduction, and commercialization; through partnerships and licensing agreements, allocating R&D resources effectively by eliminating poor programs and candidate compounds early, reducing product and process costs, mitigating noncompliance risks and reducing the cost of regulatory compliance, managing effectively the change to products, packaging components, and processes, and outsourcing without losing visibility and control of costs and risks across product lines and partners, cut direct material and operating costs, minimize the cost of managing product variations and extensions, and so on and so forth²³. In this aspect, Artificial Intelligence (AI) may help. With rapid advances in scientific technology, a wide range of medical data is being accumulated, which will be useful in developing next-generation medical care to deliver precise and optimal care to patients, in combination with advances in AI to evaluate, analyze, and apply the medical information in the clinic²⁴. Of course, we need to consider the impact of the equally fascinating warp speed evolution transforming our ecology, for predicting when we might go extinct²⁵.

In addition, as discussed above, drug discovery involves various areas of expertise²⁶ comprising synthetic organic chemistry, molecular and cellular biology, in vitro and in vivo pharmacology and toxicology, clinical research and testing, engineering, computer science, bioinformatics, high throughput screening, in silico modeling, analytical sciences and crystallography, and so on, including basic science and blue sky research²⁷ leading to major ground-breaking contributions many years later with economic gains difficult to quantify in a quarterly report, all required to help integrate new advances in technologies and old fundamentals to develop new expensive products of precision medicine²⁸ (visit NIH Funding Opportunities page²⁹) which must be more effective and better than the existing products, with less or no side effects, as new drugs are evaluated for safety, efficacy, and manufacturing quality as a condition of market access and exclusivity³⁰.

"An especially fertile area for basic or "blue-sky" research is, of course, the brain. This has been left last by scientists because of the enormous technical difficulties of studying the brain. The kind of exploration of how nerves work and how brain cells communicate with each other is being studied by Dr. Bazan's Neuroscience Center and is vital for our future understanding of how the brain works. Without it, we shall not find effective cures for strokes and neurological diseases, such as Alzheimer's, as well as problems, such as schizophrenia, epilepsy, and depression that are so empirically treated by present-day drugs." Sir John Vane, FRS (1927 – 2004), Nobel Laureate (Physiology / Medicine, 1982) (Blue-Sky Research)

Issue 241	5118 కలి కాలము/Kali Era 2074 విక్రమార్క కాలము/Vikramarka Era 1938 శాలివాహన కాలము/Salivahana Era స్వస్తి శ్రీ హేవలంబి నామ సంవత్సరము/स्वस्ति श्री हेविलम्बी नाम संवत्सर/ Swasti Sri Hevilambi Year మాఘమాసము/MAGHA Month Published online 1 FEBRUARY 2018
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Home	The Foundation	Management	The Andhra Journal of Industrial News	The Telangana Science Journal	Mana Sanskriti (Our Culture)
Vegetarian Links	Disclaimer	Solicitation	Contact	VPC	Vedah-net

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ॐ भूर्भुवः स्वः तत्सवितुर्वरेण्यं भर्गो देवस्य धीमहि धियो यो नः प्रचोदयात् ॥

Home	The Foundation	Management	The Andhra Journal of Industrial News	The Telangana Science Journal	Mana Sanskriti (Our Culture)
Vegetarian Links	Disclaimer	Solicitation	Contact	VPC	Vedah-net

Issue 241

Chief Editor: డాక్టర్ శ్రీనివాసరావు వేపచేదు | डॉक्टर श्रीनिवासरारवु वेपचेदु | Dr. Sreenivasarav Vepachedu¹

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²² Shares of Houston-based Bellicum Pharmaceuticals plunged more than 48 percent in aftermarket trading after the company announced the U.S. Food and Drug Administration slapped a clinical hold on its lead cell therapy product after three cases of encephalopathy were reported. <https://www.biospace.com/article/unique-3-cases-of-brain-damage-force-the-fda-to-slap-a-hold-on-bellicum-s-lead-drug/>

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Investors Elated as Vertex Picks Two Top CF Triple Combos for Phase III Trials <https://www.biospace.com/article/unique-investors-elated-as-vertex-picks-two-top-cf-triple-combos-for-phase-iii-trials/>

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Issue 241	5118 కలి కాలము/Kali Era 2074 విక్రమార్క కాలము/Vikramarka Era 1938 శాలివాహన కాలము/Salivahana Era స్వస్తి శ్రీ హేవిళంబి నామ సంవత్సరము/स्वस्ति श्री हेविलम्बी नाम संवत्सर/Swasti Sri Hevilambi Year మాఘమాసము/MAGHA Month Published online 1 FEBRUARY 2018
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ॐ असतो मा सद्गमय । तमसो मा ज्योतिर्गमय । मृत्योर्मा अमृतं गमय । ॐ शान्तिः शान्तिः शान्तिः ॥

O Sun God, Savitr!
Thou dazzling fount of life-persuasive light!
Sublimest mystery speeding from afar!
Swift became that burst too potent on the sight!
This radiant type of strength and youth!
Glowing eternally!



శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Telangana Science Journal

Health and Nutrition

TIACS-subscribe@yahoo.com (The Indian American Chemical Society)

He alone shines!
All luminaries get illuminated by His Illumination!
The whole Universe is enlightened by His light!
- Kathapanisad

May the golden-eyed Savitar, come hither!
Shining forth he rises from the lap of the dawn!
Praised by singers, my God Savitar!
Stepped forth and never missed his place!
He steps forth the splendor of the sky the wide!
Seeing, far-shining, the shining wanderer!
- Rig Veda, vii, 65

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Home	The Foundation	Management	The Andhra Journal of Industrial News	The Telangana Science Journal	Mana Sanskriti (Our Culture)
Vegetarian Links	Disclaimer	Solicitation	Contact	VPC	Vedah-net

Issue 241

Chief Editor: డాక్టర్ శ్రీనివాసరావు వేపచేదు | डॉक्टर श्रीनिवासरावु वेपचेदु | Dr. Sreenivasarao Vepachedu¹

²⁶ Adams, Drug discovery and development: A complex team sport, a Science Advertising Feature (March 7, 2008) <http://www.sciencemag.org/features/2008/03/drug-discovery-and-development-complex-team-sport>

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'Blue Sky' Basic Science Leads to Breakthrough Innovation and a Nobel Prize <https://research.northwestern.edu/vp-views/%E2%80%98blue-sky%E2%80%99-basic-science-leads-breakthrough-innovation-%E2%80%94-and-nobel-prize>

Seven UCSF Scientists Receive NIH 'Blue-Sky' Research Awards, High-Risk, High-Reward Research Program Supports 'Creative', 'Bold' Scientists Tackling Major Biomedical Challenges

<https://www.ucsf.edu/news/2016/10/404461/seven-ucsf-scientists-receive-nih-blue-sky-research-awards>

Science and our economy: the (blue) sky's the limit, SCIENCE & TECH (30 NOVEMBER 2012)

<https://www.newstatesman.com/sci-tech/sci-tech/2012/11/science-and-our-economy-blue-skys-limit>

²⁸ The Precision Medicine Initiative <https://obamawhitehouse.archives.gov/node/333101>

²⁹ Genome editing technologies such as CRISPR/Cas9 are revolutionizing biomedical research. The translation of these technologies to the clinic for treatment of genetic diseases requires basic research/blue sky research. Many rare diseases, as well as some common disorders, are caused by changes in a person's DNA, either through changes inherited from parents or those that occur during a person's lifetime. Advances in genome editing made over the past decade now make it possible to precisely change the DNA code inside living cells. Despite widespread interest and investment in this field, many challenges remain preventing broad adoption of this technology in the clinic. The NIH is now accepting applications for the Somatic Cell Genome Editing (SCGE) program. Applications are due April 3, 2018. For additional information on these RFAs visit NIH Funding Opportunities page <https://commonfund.nih.gov/editing/fundingopportunities>

<https://commonfund.nih.gov/editing>; The NIH Common Fund encourages collaboration and supports a series of exceptionally high-impact, trans-NIH programs. Common Fund programs are managed by the Office of Strategic Coordination in the Division of Program Coordination, Planning, and Strategic Initiatives in the NIH Office of the Director in partnership with the NIH Institutes, Centers, and Offices. More information is available at the Common Fund website: <https://commonfund.nih.gov>.

China Sees Promise, not Danger in Crispr Gene-Editing Trials <https://www.biospace.com/article/around-the-web/china-sees-promise-not-danger-in-crispr-gene-editing-trials/?s=86>

³⁰ Economics of the Pharmaceutical Industry <https://www.nber.org/reporter/fall06/danzon.html>

³¹ **Disclaimer:** Although every effort has been made to provide accurate information from reputable sources, the content of this law update is a general guide and CIP or the author is not responsible for inadvertent errors and/or any inaccuracies of the matter obtained from various resources cited therein. Specialist or registered agent's advice should be sought about your specific circumstances and specific country.

Issue 241	5118 కలి కాలము/Kali Era 2074 విక్రమార్క కాలము/Vikramarka Era 1938 శాలివాహన కాలము/Salivahana Era स्वस्ति श्री हेविलम्बी नाम संवत्सर/Swasti Sri Hevilambi Year మాఘమాసము/MAGHA Month Published online 1 FEBRUARY 2018
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