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!

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

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IP and Industry News

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Issue 161

Dr. Sreenivasarao Vepachedu[1], JD, PhD, LLM

CANCER DRUG DEVELOPMENT
The Global Fight Against Cancer

THE DISCOVERY OF NEW DRUGS is a long, arduous and expensive process. It involves testing various chemical entities obtained from natural products from plants, fungi, and animals, and synthetic chemicals based on the structure of a drug target such as proteins, enzymes, receptors etc., involved in the disease, using computers to mimic how a potential drug interacts with its target to design chemical compounds that interact with the specific drug target.

Once a lead compound is identified for a disease or disorder, medicinal chemists optimize the lead using the computer models fine tuning the chemical-target interaction to identify a drug candidate, which will go through preclinical studies in animals and several phases of FDA approved clinical trials in humans to make sure the drug is safe to humans through an Investigational New Drug (IND) application[2]. The FDA approves potential drugs for testing in people if the research presented in the IND application shows that the drug is likely to work and be safe. Once the IND app is successful, a New Drug Application (NDA) is submitted to the FDA requesting approval of the drug for physician prescribing. The NDA contains results from the preclinical and clinical studies and details about how the drug will be made and labeled, and the drug's possible side effects and any interactions with food or other drugs.

To speed up this process, the FDA has several programs to help new drugs reach patients faster such as fast track program, designation of breakthrough therapy, accelerated approval, priority review[3]. Patients For Affordable Drugs is an independent national patient organization focused exclusively on achieving policy changes to lower the price of prescription drugs under the belief that the prescription drug pricing system in the US is rigged against patients,[4] but there is no other country in the world that contributes to the drug discovery for the benefit of the entire humanity with constitutionally mandated[5] short-term (a maximum term of 20-year) monopolies over novel and non-obvious inventions.

War on Cancer: Cancer is a leading cause of death, and cancer incidence is expected to increase worldwide, as the populations' life-span increases. In 1971, President Richard Nixon launched what was a called a "War on Cancer." In addition to the FDA's programs to encourage drug applications, the United States Patent and Trademark Office (USPTO) provides fast-track and special options for many inventions related drug development. But curing cancer turned out to be much more complicated than putting men on the moon.

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Therefore, President Obama launched **National Cancer Moonshot** lead by Vice President Joe Biden,[6] for who this challenge is personal. The cancer moonshot is a $ 1 bn injection of cash intended to bring a decade's worth of advances in just five years[7].

To support the $1 billion National Cancer Moonshot initiative launched on February 1, 2016, the USPTO established a pilot program called Patents 4 Patients, also known as the Cancer Immunotherapy Pilot Program. Patents 4 Patients established a free Fast-Track Review for cancer treatment-related patents to cut in half the time it takes to review patent applications in cancer therapy aiming to have final decisions made in 12 or fewer months is open to any applicant, including early stage bio-tech companies, universities, and large pharmaceutical firms, as well as entities who may have products already in FDA approved clinical trials, even if they have a patent application already filed with the office.

With approximately 900 cancer immunotherapy applications received annually by the USPTO, and from around the world, this program aims to move innovative new treatments from conception through regulatory approval swiftly, to reach a patient's bedside faster. The USPTO has extended the pilot program until December 31, 2018[8]. To participate in this program to avail the free fast-track opportunity, a Certification and petition to make special under the cancer immunotherapy pilot program (Form PTO/SB/443) is needed.

Cancer is a class of diseases characterized by out-of-control cell growth forming lumps or masses of tissue called tumors. Tumors that stay in one spot and demonstrate limited growth are generally considered to be benign. When a tumor successfully spreads to other parts of the body and grows, invading and destroying other healthy tissues, it is said to have metastasized. There are over 100 different types of cancer classified by the type of cell that is initially affected. Blood cancer is due to white blood cells (WBC) that fight germs. WBC are produced in marrow and the spongy tissue inside some of your bigger bones. The abnormal WBCs are known as myeloma cells and may form a single tumor called solitary *plasmacytoma* or form more than one tumor called multiple myeloma.

The lymphatic system comprising lymph nodes helps the body fight off infection by filtering out bacteria and viruses. Cancers that attack the lymphatic system are known as lymphomas, Hodgkin's and non-Hodgkin's, the most common kind of blood cancers. The difference between the two types of lymphoma is in the lymphocyte that's involved. With Hodgkin's lymphoma, your body makes a kind called Reed-Sternberg cells, one of the most curable forms of cancer.

Leukemia can occur in either the lymphoid or myeloid white blood cells. Cancer that develops in the lymphoid cells is called lymphocytic leukemia. Cancer that develops in the myeloid cells is called myelogenous leukemia. The disease can be either acute (begins abruptly and is usually short lived) or chronic (persists for a long period of time). Plasma cell leukemia (PCL) is an aggressive form of multiple myeloma characterized by high levels

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of abnormal plasma cells circulating in the peripheral (circulating) blood. Normal plasma cells in the bone marrow produce antibodies that fight infection.

Red blood cells carry oxygen, and white blood cells fight disease. Platelets help clot blood to patch up a cut. Some types of cancer affect the parts of the body that make these things, including leukemia, lymphomas, and myelomas. More than 171,000 people were diagnosed with blood cancers in 2016. Multiple myeloma twice as common in African-Americans and slightly more likely to affect men than women. According to the American Cancer Society, Cancer is the second most common cause of death in the US and accounts for nearly 1 of every 4 deaths. The World Health Organization estimates that, worldwide, there were 14 million new cancer cases and 8.2 million cancer-related deaths in 2012[9]. Of 1.7 million new cases diagnosed each year in the US, at least one third could be prevented by simple changes to diet and clothes.

In leukemia, myeloma cells may prevent bone marrow from making other blood cells such as white blood cells, red blood cells, osteoblasts, and platelets. Myeloma cells are also responsible for impairing antibody production to fight germs.

- Anemia (low red blood cells), which can cause fatigue,
- Thrombocytopenia (low platelets), which can cause bruising or bleeding,
- Leukopenia (low white blood cells), which raises infection risk,
- Born fractures, bones get weak and can fracture easily due to low osteoblast production, and
- Infections, as myeloma cells multiply and quickly crowd out your healthy plasma cells, along with other white blood cells that protect the body from infection

Multiple myeloma can lead to health problems like confusion and dizziness, numbness or muscle weakness in your legs, and kidney problems. Myeloma may be diagnosed by blood tests to check low blood cell counts and high calcium levels, X-rays to reveal bone loss, and a bone marrow biopsy to see if you have myeloma cells. Treatment may include immunomodulating agents to affect your immune system, proteasome inhibitors to stop cells from breaking down proteins monoclonal antibodies to attack cells that are a threat. Other possible treatments include a stem cell transplantation either autologous or allogeneic.

Food and Drug Administration (FDA)[10] initiated efforts in 1997 and supported by requirements in section 403 of the Modernization Act of 1997 to improve the FDA's process for approving supplemental applications and facilitate the addition of safe and effective new uses for the treatment of cancer to drug labeling.

Product labeling is intended to provide full prescribing information for a product and should include all clinical indications for which adequate data are available to establish the product's safety and effectiveness. Many newer uses of anticancer products are common in clinical practice, but are not listed in product labeling, despite the fact that they appear to be supported by published data from clinical studies.

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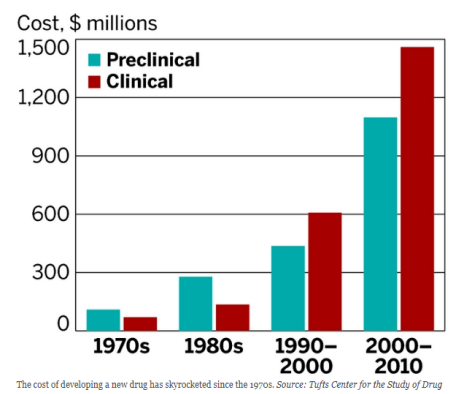
But there are substantial disincentives, including (1) the cost and effort involved in completing new research where necessary to verify whether a product provides patient benefit in a new indication; (2) the cost and effort involved in submitting an application for regulatory approval of new clinical uses; and (3) the lack of perceived commercial benefit of revised labeling if the product is already being used for the new indication, especially if it no longer has patent protection.

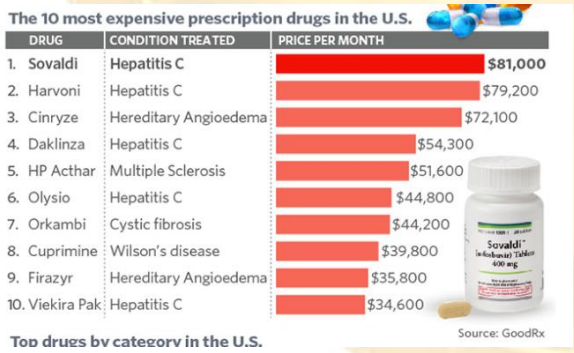
Supplemental applications for new cancer treatment uses will receive priority review if, based on preliminary review of the application, it appears that the new product use may represent a significant improvement compared to other marketed products in the treatment, diagnosis, or prevention of a disease. The fact that a product is already marketed for another indication does not affect FDA's determination of whether a new supplemental application receives priority review. The Oncology Branch of the Division of Clinical Trials Design and Analysis works with sponsors to facilitate the development and submission of data to support supplemental applications for biologics used in cancer treatment.

Currently, incentives exist for holders of approved marketing applications to submit supplemental applications for new uses for their marketed products. To date, the net effect of the incentives and disincentives has been that relatively few supplemental applications have been submitted for new uses of marketed cancer treatment products. New technologies such as gene and cell therapies hold out the potential to transform medicine and create an inflection point in our ability to treat and even cure many intractable illnesses.



The cost of developing a new drug has skyrocketed since the 1970s. *Source: Tufts Center for the Study of Drug Development.*

A rapidly emerging immunotherapy[11] approach is called adoptive cell transfer (ACT): collecting and using patients' own immune cells to treat their cancer. There are several types of ACT such as TILs, TCRs, and CARs. In July, an FDA panel opened a new era in medicine unanimously recommending that the agency approve personalized drug based on Kymriah[12] or tisagenlecleucel, the first-ever treatment that genetically alters a patient's own cells to fight cancer bolstering the immune system against the disease. Kymriah is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of patients up to 25 years of age with B-cell precursor Acute Lymphoblastic Leukemia (ALL) that



Issue 161

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era
Swasti Sri **HEVILAMBI** Year, **BHADRAPADA** Month
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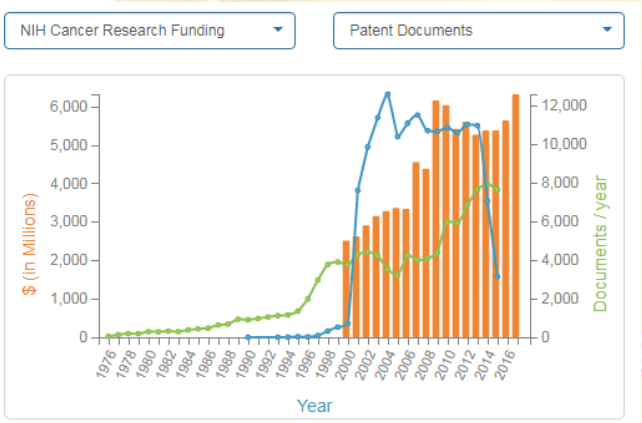
is refractory or in second or later relapse. Each patient's immune system T cells are removed, programmed to attack acute lymphoblastic leukemia cells, then returned to the patient. The market for the drug is relatively small, about 600 children a year in the United States may be candidates. The price tag $475,000 for a course of treatment.



Super pricey medications for small populations can be quite successful commercially. Gilead launched the infamous $ 1,000 per pill hep C drug Sovaldi in 2014, and followed that up with the even costlier Harvoni the next year. Sovaldi could actually hit $ 4.5 billion next year, or more than $1 billion per quarter, on average. Pharmaceutical industry's pricing strategy has always been focused on maximizing revenue as that is the only way to pay for the cost of developing new drugs. Without that incentive, there would not have been so many drugs developed in this country for the benefit of the entire world. The American tax payers also contribute their hard earned money towards the basic research on diseases and disorders that is the basis for the development of novel drugs, e.g., NIH spent about $ 6 billion on cancer research resulting in about 12,000 patent documents in 2016 (see the figure[13]).

The Tufts Center for the Study of Drug Development (CSDD) pegs the cost of developing a prescription drug that gains market approval at $2.6 billion, a 145% increase[14], correcting for inflation, over the estimate the center made in 2003. This is not an excuse for high price of new drugs, but it is reality of the drug development with stringent clinical trials requiring better efficacy shown than the existing drugs.

Drugs Approved in 2017

1. **Aliqopa** (copanlisib): Bayer's copanlisib for the treatment of follicular lymphoma, approved September 2017.
2. **Verzenio** (abemaciclib): Eli Lilly; For the treatment of HR+, HER2- breast cancer, Approved September 2017
3. **Kymriah** (tisagenlecleucel): Novartis; For the treatment of refractory B-cell precursor acute lymphoblastic leukemia, Approved August 2017

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4. **Besponsa** (inotuzumab ozogamicin): Pfizer's for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia, approved August 2017.
5. **Idhifa** (enasidenib): Celgene's treatment of relapsed or refractory acute myeloid leukemia with IDH2 mutation, approved August 2017.
6. **Vyxeos** (daunorubicin and cytarabine): Jazz Pharma; For the treatment of newly-diagnosed therapy-related AML or AML with myelodysplasia-related changes, Approved August 2017
7. **Nerlynx** (neratinib): Puma Biotech; For the treatment of HER2 breast cancer, Approved July 2017
8. **Imfinzi** (durvalumab): AstraZeneca's treatment of advanced or metastatic urothelial carcinoma, Approved May 2017.
9. **Alunbrig** (brigatinib): Ariad Pharmaceuticals' for the treatment of advanced ALK-positive metastatic non-small cell lung cancer, approved April 2017.
10. **Rydapt** (midostaurin): Novartis; For the treatment of FLT3 positive acute myeloid leukemia and mastocytosis, Approved April 2017
11. **Bavencio** (avelumab): EMD Serono/Pfizer's for the treatment of Merkel cell carcinoma, approved March 2017.
12. **Kisqali** (ribociclib): Novartis's treatment of breast cancer, approved March 2017.
13. **Zejula** (niraparib): Tesaro; For the treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, Approved March 2017
14. **Xermelo** (telotristat ethyl): Lexicon Pharmaceuticals; For the treatment of carcinoid syndrome diarrhea, Approved February 2017

Drugs Approved in 2016

15. **Cabometyx** (cabozantinib): Exelixis; For the treatment of advanced renal cell carcinoma, Approved April 2016
16. **Keytruda** (pembrolizumab): Merck; For the treatment of head and neck squamous cell cancer, Approved August 2016
17. **Lartruvo** (olaratumab): Eli Lilly; For the treatment of soft tissue sarcoma, Approved October 2016
18. **Lenvima** (lenvatinib): Eisai; For the treatment of advanced renal cell carcinoma, Approved May 2016
19. **Opdivo** (nivolumab): Bristol-Myers Squibb; For the treatment of classical Hodgkin lymphoma, Approved May 2016
20. **Rubraca** (rucaparib): Clovis Oncology; For the treatment of advanced ovarian cancer in women with deleterious germline or somatic BRCA mutation, Approved December 2016

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21. **Sustol** (granisetron): Heron Therapeutics; For the prevention of chemotherapy-induced nausea and vomiting, Approved August 2016
22. **Syndros** (dronabinol oral solution): Insys Therapeutics; For the treatment of anorexia associated with AIDS and nausea and vomiting associated with cancer chemotherapy, Approved July 2016
23. **Tecentriq** (atezolizumab): Genentech; For the treatment of urothelial carcinoma and metastatic non-small cell lung cancer, Approved May 2016
24. **Venclexta** (venetoclax): AbbVie; For the treatment of chronic lymphocytic leukemia with 17p deletion, Approved April 2016

Drugs Approved in 2015

25. **Alecensa** (alectinib): Roche; For the treatment of ALK-positive, metastatic non-small cell lung cancer, Approved December 2015
26. **Cotellic** (cobimetinib): Genentech; For the treatment of BRAF V600E or V600K melanoma, Approved November 2015
27. **Darzalex** (daratumumab): Janssen Biotech; For the treatment of multiple myeloma, Approved November 2015
28. **Empliciti** (elotuzumab): Bristol-Myers Squibb; For the treatment of patients with multiple myeloma who have received prior therapies, Approved November 2015
29. **Farydak** (panobinostat): Novartis; For the treatment of multiple myeloma, Approved February 2015
30. **Ibrance** (palbociclib): Pfizer; For the treatment of ER-positive, HER2-negative breast cancer, Approved February 2015
31. **Imlygic** (talimogene laherparepvec): Amgen; For the treatment of unresectable recurrent melanoma, Approved October 2015
32. **Keytruda** (pembrolizumab): Merck; For the treatment of PD-L1 positive advanced non-small cell lung cancer, Approved October 2015
33. **Lenvima** (lenvatinib): Eisai; For the treatment of thyroid cancer, Approved February 2015
34. Lonsurf (trifluridine and tipiracil): Taiho Oncology; For the treatment of metastatic colorectal cancer, Approved September 2015
35. **Ninlaro** (ixazomib): Millennium Pharmaceuticals; For the treatment of multiple myeloma, Approved November 2015
36. **Odomzo** (sonidegib): Novartis; For the treatment of locally advanced basal cell carcinoma, July 2015
37. **Onivyde** (irinotecan liposome injection): Merrimack; For the treatment of metastatic pancreatic cancer following gemcitabine-based therapy, Approved October 2015

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38. **Opdivo** (nivolumab): Bristol-Myers Squibb; For the treatment of advanced renal cell carcinoma, Approved November 2015
39. **Opdivo** (nivolumab): Bristol-Myers Squibb; For the treatment of metastatic squamous non-small cell lung cancer, Approved March 2015
40. **Portrazza** (necitumumab): Eli Lilly; For the treatment of metastatic squamous non-small cell lung cancer, Approved November 2015
41. **Tagrisso** (osimertinib): AstraZeneca; For the treatment of EGFR T790M mutation positive non-small cell lung cancer, Approved November 2015
42. **Unituxin** (dinutuximab): United Therapeutics; For the treatment of pediatrics with high-risk neuroblastoma, Approved March 2015
43. **Varubi** (rolapitant): Tesaro; For the prevention of delayed nausea and vomiting associated with chemotherapy, Approved September 2015
44. **Vistogard** (uridine triacetate): Wellstat Therapeutics; For the emergency treatment of patients with a fluorouracil or capecitabine overdose, Approved December 2015
45. **Yondelis** (trabectedin): Janssen; For the treatment of liposarcoma or leiomyosarcoma, Approved October 2015

Drugs Approved in 2014

46. Akynzeo (netupitant and palonosetron): Helsinn; For the prevention of chemotherapy-induced nausea and vomiting, Approved October 2014
47. Beleodaq (belinostat): Spectrum Pharmaceuticals; For the treatment of relapsed or refractory peripheral T-cell lymphoma, Approved July 2014
48. Blincyto (blinatumomab): Amgen; For the treatment of Philadelphia chromosome-negative relapsed /refractory B cell precursor acute lymphoblastic leukemia, Approved December 2014
49. Cyramza (ramucirumab): Eli Lilly; For the treatment of gastric cancer, Approved April 2014
50. Imbruvica (ibrutinib): Pharmacyclics; For the treatment of chronic lymphocytic leukemia and Waldenstrom macroglobulinemia, Approved February 2014
51. Keytruda (pembrolizumab): Merck; For the treatment of unresectable or metastatic melanoma, Approved September 2014
52. Lynparza (olaparib): AstraZeneca; For the treatment of previously treated BRCA mutated advanced ovarian cancer, Approved December 2014
53. Opdivo (nivolumab): Bristol-Myers Squibb; For the treatment of unresectable or metastatic melanoma, Approved December 2014

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54. Zydelig (idelalisib): Gilead; For the treatment of relapsed CLL, follicular B-cell NHL and small lymphocytic lymphoma, Approved July 2014
55. Zykadia (ceritinib): Novartis; For the treatment of ALK+ metastatic non-small cell lung cancer, Approved April 2014

Drugs Approved in 2013

56. **Gazyva** (obinutuzumab): Genentech; For the treatment of previously untreated chronic lymphocytic leukemia, Approved October of 2013
57. **Gilotrif** (afatinib): Boehringer Ingelheim; For the treatment of metastatic non-small cell lung cancer with EGFR mutations, Approved July 2013
58. **Imbruvica** (ibrutinib): Pharmacyclics; For the treatment of mantle cell lymphoma, Approved November of 2013
59. **Kadcyla** (ado-trastuzumab emtansine): Genentech; For the treatment of HER2-positive metastatic breast cancer, Approved February 2013
60. **Mekinist** (trametinib): GlaxoSmithKline; For the treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutations, Approved May of 2013
61. **Pomalyst** (pomalidomide): Celgene; For the treatment of relapsed and refractory multiple myeloma, Approved February 2013
62. **Revlimid** (lenalidomide): Celgene; For the treatment of mantle cell lymphoma, Approved June 2013
63. **Stivarga** (regorafenib): Bayer; For the treatment of gastrointestinal stromal tumor, Approved February 2013
64. **Tafinlar** (dabrafenib): GlaxoSmithKline; For the treatment of unresectable or metastatic melanoma with BRAF V600E mutation, Approved May 2013
65. **Valchlor** (mechlorethamine) gel; Ceptaris Therapeutics; For the treatment of Stage IA/IB mycosisfungoides-type cutaneous T-cell lymphoma, Approved August 2013
66. **Xgeva** (denosumab): Amgen; For the treatment of giant cell tumor of bone, Approved June 2013
67. **Xofigo** (radium Ra 223 dichloride): Bayer Healthcare Pharmaceuticals; For the treatment of prostate cancer with bone metastases, Approved May 2013

Drugs Approved in 2012

68. **Abraxane** (paclitaxel protein-bound particles for injectable suspension): Celgene; For the treatment of non-small cell lung cancer, Approved October 2012

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69. **Afinitor** (everolimus): Novartis; For the treatment of renal angiomyolipoma associated with tuberous sclerosis complex, Approved April 2012
70. **Afinitor** (everolimus): Novartis; For the treatment of hormone receptor-positive, HER2-negative breast cancer, Approved July 2012
71. **Bosulif** (bosutinib): Pfizer; For the treatment of Ph+ chronic myelogenous leukemia, Approved September 2012
72. **Cometriq** (cabozantinib): Exelixis; For the treatment of metastatic medullary thyroid cancer, Approved November 2012
73. **Erivedge** (vismodegib): Genentech; For the treatment of basal cell carcinoma, Approved January 2012
74. **Iclusig** (ponatinib): Ariad Pharmaceuticals; For the treatment of chronic myeloid leukemia and Philadelphia chromosome positive acute lymphoblastic leukemia, Approved December 2012
75. **Inlyta** (axitinib): Pfizer; For the treatment of advanced renal cell carcinoma, Approved January 2012
76. **Kyprolis** (carfilzomib): Onyx Pharmaceuticals; For the treatment of multiple myeloma, Approved July 2012
77. **Marqibo** (vinCRIStine sulfate LIPOSOME injection): Talon Therapeutics; For the treatment of Ph- acute lymphoblastic leukemia, Approved August 2012
78. **Neutroval** (tbo-filgrastim): Teva Pharmaceutical; For the reduction in the duration of severe chemotherapy-induced neutropenia, Approved August 2012
79. **Perjeta** (pertuzumab): Genentech; For the first-line treatment of HER2+ metastatic breast cancer, Approved June 2012
80. **Picato** (ingenol mebutate) gel; LEO Pharma; For the treatment of actinic keratosis, Approved January 2012
81. **Stivarga** (regorafenib): Bayer HealthCare Pharmaceuticals; For the treatment of previously treated patients with metastatic colorectal cancer, Approved September 2012
82. **Subsys** (fentanyl sublingual spray): Insys Therapeutics; For the treatment of breakthrough cancer pain, Approved January of 2012
83. **Synribo** (omacetaxine mepesuccinate): Teva Pharmaceutical; For the treatment of chronic or accelerated phase chronic myeloid leukemia, Approved October 2012
84. **Votrient** (pazopanib): GlaxoSmithKline; For the treatment of soft tissue sarcoma, Approved April 2012
85. **Xtandi** (enzalutamide): Medivation; For the treatment of metastatic castration-resistant prostate cancer, Approved August 2012
86. **Zaltrap** (ziv-aflibercept): Sanofi-aventis; For the treatment of metastatic colorectal cancer, Approved August 2012

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87. Drugs Approved in 2011
88. **Abstral** (fentanyl sublingual tablets): ProStrakan; For the treatment of breakthrough cancer pain in opioid-tolerant patients, Approved January 2011
89. **Adcetris** (brentuximab vedotin): Seattle Genetics; For the treatment of Hodgkin lymphoma and anaplastic large cell lymphoma, Approved August 2011
90. **Afinitor** (everolimus): Novartis; For the treatment of advanced pancreatic neuroendocrine tumors, Approved May 2011
91. **Erwinaze** (asparaginase Erwinia chrysanthemi): Eusa Pharma; For the treatment of acute lymphoblastic leukemia,
92. Approved November of 2011
93. **Lazanda** (fentanyl citrate) nasal spray; Archimedes; For the management of breakthrough cancer pain, Approved June 2011
94. **Sutent** (sunitinib malate): Pfizer; For the treatment of pancreatic neuroendocrine tumors, Approved May 2011
95. **Sylatron** (peginterferon alfa-2b): Merck; For the treatment of melanoma, Approved April 2011
96. **Vandetanib** (vandetanib): AstraZeneca; For the treatment of thyroid cancer, Approved April 2011
97. **Xalkori** (crizotinib): Pfizer; For the treatment of ALK+ non-small cell lung cancer, Approved August of 2011
98. **Yervoy** (ipilimumab): Bristol-Myers Squibb; For the treatment of metastatic melanoma, Approved March 2011
99. **Zelboraf** (vemurafenib): Roche; For the treatment of BRAF + melanoma, Approved August of 2011
100. **Zytiga** (abiraterone acetate): Centocor Ortho Biotech; For the treatment of prostate cancer, Approved May 2011

Drugs Approved in 2010

101. **Halaven** (eribulin mesylate): Eisai; For the treatment of metastatic breast cancer, Approved November 2010
102. **Herceptin** (trastuzumab): Genentech; For the treatment of gastric cancer, Approved October 2010
103. **Jevtana** (cabazitaxel): sanofi aventis; For the treatment of prostate cancer, Approved June 2010
104. **Provenge** (sipuleucel-T): Dendreon; For the treatment of hormone refractory prostate cancer, Approved May 2010
105. **Xgeva** (denosumab): Amgen; For the prevention of skeletal-related events in patients with bone metastases from solid tumors, Approved November 2010

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106. **Zuplenz** (ondansetron oral soluble film): Strativa Pharmaceuticals; For the prevention of post-operative, chemotherapy and radiotherapy induced nausea and vomiting, Approved July 2010

Drugs Approved in 2009

107. **Afinitor** (everolimus): Novartis; For the treatment of renal cell carcinoma, Approved March 2009
108. **Arzerra** (ofatumumab): GlaxoSmithKline; For the treatment of chronic lymphocytic leukemia, Approved October 2009
109. **Avastin** (bevacizumab): Genentech; For the treatment of renal cell carcinoma, Approved July 2009
110. **Cervarix** [Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant; GlaxoSmithKline; For the prevention of cervical cancer and cervical intraepithelial neoplasia caused by HPV types 16 and 18, Approved October 2009
111. **Elitek** (rasburicase): sanofi-aventis; For the management of plasma uric acid levels in adults with malignancies, Approved October 2009
112. **Folotyn** (pralatrexate injection): Allos Therapeutics; For the treatment of peripheral T-cell lymphoma, Approved September 2009
113. **Istodax** (romidepsin): Gloucester Pharmaceuticals; For the treatment of cutaneous T-cell lymphoma, Approved November 2009
114. **Onsolis** (fentanyl buccal): BioDelivery Sciences; For the management of breakthrough cancer pain, Approved July 2009
115. **Votrient** (pazopanib): GlaxoSmithKline; For the treatment of renal cell carcinoma, Approved October of 2009

Drugs Approved in 2008

116. **Degarelix** (degarelix for injection): Ferring Pharmaceuticals; For the treatment of prostate cancer, Approved December of 2008
117. **Fusilev** (levoleucovorin): Spectrum Pharmaceuticals; For rescue after high-dose methotrexate therapy in osteosarcoma and to reduce the toxicity of methotrexate, Approved March of 2008
118. **Mozobil** (plerixafor injection): Genzyme; For the treatment of non-Hodgkin's lymphoma and multiple myeloma, Approved December 2008
119. **Sancuso** (granisetron): ProStrakan; For the treatment of chemotherapy-induced nausea and vomiting, Approved September 2008
120. **Treanda** (bendamustine hydrochloride): Cephalon; For the treatment of Chronic lymphocytic leukemia and B-cell non-Hodgkin's lymphoma, Approved October 2008

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

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Drugs Approved in 2007

121. **Evista** (raloxifene hydrochloride): Eli Lilly; For the treatment/prevention of osteoporosis and reduction of breast cancer risk in postmenopausal women, Approved September 2007
122. **Hycamtin** (topotecan hydrochloride): GlaxoSmithKline; For the treatment of small cell lung cancer, Approved October 2007
123. **Ixempra** (ixabepilone): Bristol-Myers Squibb; For the treatment of breast cancer, Approved October 2007
124. **Tasigna** (nilotinib hydrochloride monohydrate): Novartis; For the treatment of chronic myelogenous leukemia, Approved October 2007
125. **Torisel** (temsirolimus): Wyeth; For the treatment of renal cell carcinoma, Approved May 2007
126. **Tykerb** (lapatinib): GlaxoSmithKline; For the treatment of breast cancer, Approved March 2007

Drugs Approved in 2006

127. **Gardasil** (quadrivalent human papillomavirus (types 6, 11, 16, 18) recombinant vaccine): Merck; For the prevention of cervical cancer associated with human papillomavirus, Approved June 2006
128. **Sprycel** (dasatinib): Bristol-Myers Squibb; For the treatment of imatinib-resistant chronic myeloid leukemia, Approved June 2006
129. **Sutent** (sunitinib): Pfizer; For the treatment of kidney cancer and gastrointestinal stromal tumors, Approved January 2006
130. **Vectibix** (panitumumab): Amgen; For the treatment of colorectal cancer, Approved September 2006

Drugs Approved in 2005

131. **Arranon** (nelarabine): GlaxoSmithKline; For the treatment of T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma, Approved October 2005
132. **Nexavar** (sorafenib): Bayer/Onyx; For the Treatment of Renal Cell Carcinoma, Approved December 2005

Drugs Approved in 2004

133. **Alimta** (pemetrexed for injection): Eli Lilly; For the treatment of malignant pleural mesothelioma, Approved February 2004

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5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era
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134. **Avastin** (bevacizumab): Genentech; For the treatment of metastatic carcinoma of the colon or rectum, Approved February 2004
135. **Clolar** (clofarabine): Genzyme; For the treatment of acute lymphoblastic leukemia in pediatric patients, Approved December, 2004
136. **Erbitux** (cetuximab): Imclone, Bristol-Myers Squibb; For the treatment of EGFR-expressing, metastatic colorectal cancer, Approved February 2004
137. **Sensipar** (cinacalcet): Amgen; For the treatment of secondary hyperparathyroidism and hypercalcemia in parathyroid carcinoma patients, Approved March 2004
138. **Tarceva** (erlotinib, OSI 774): Genentech, OSI Pharmaceuticals; For the treatment of advanced refractory metastatic non-small cell lung cancer, Approved November, 2004

Drugs Approved in 2003

139. **Aloxi** (palonosetron): MGI Pharma, Helsinn Healthcare; For the prevention of nausea and vomiting associated with emetogenic cancer chemotherapy, Approved August 2003
140. **Bexxar**; Corixa; For the treatment of patients with CD20 positive, follicular, non-Hodgkin's lymphoma following chemotherapy relapse, Approved June 2003
141. **Emend** (aprepitant): Merck; For the treatment of nausea and vomiting associated with chemotherapy, Approved March 2003
142. **Iressa** (gefitinib): AstraZeneca; For the second-line treatment of non-small-cell lung cancer, Approved May 2003
143. **Plenaxis** (abarelix for injectable suspension): Praecis Pharmaceuticals; For treatment of advanced prostate cancer, Approved December 2003
144. **Premarin** (conjugated estrogens): Wyeth; For the prevention of postmenopausal osteoporosis and treatment of vasomotor menopause symptoms, Approved July of 2003
145. **UroXatral** (alfuzosin HCl extended-release tablets): Sanofi-aventis; For the treatment of of the signs and symptoms of benign prostatic hyperplasia, Approved June 2003
146. **Velcade** (bortezomib): Millennium Pharmaceuticals; Injectable agent for the treatment of multiple myeloma patients who have received at least two prior therapies., Approved May 2003

Drugs Approved in 2002

147. **Eligard** (leuprolide acetate): Atrix Laboratories; For the palliative treatment of advanced prostate cancer, Approved January 2002

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148. **Eloxatin** (oxaliplatin/5-fluorouracil/leucovorin): Sanofi-aventis; For the treatment of colon or rectum carcinomas, Approved August 2002
149. **Faslodex** (fulvestrant): AstraZeneca; For the treatment of hormone receptor positive metastatic breast cancer, Approved April 2002
150. **Gleevec** (imatinib mesylate): Novartis; For the treatment of gastrointestinal stromal tumors (GISTs), Approved February 2002
151. **Neulasta**; Amgen; Treatment to decrease the chance of infection by febrile neutropenia in patients receiving chemotherapy, Approved January 2002
152. SecreFlo (secretin): Repligen; To aid in the diagnosis of pancreatic dysfunction and gastrinoma, Approved April 2002
153. Zevalin (ibritumomab tiuxetan): Biogen IDEC; For the treatment of non-Hodgkin's lymphoma, Approved February 2002
154. Zometa (zoledronic acid): Novartis; For the treatment of multiple myeloma and bone metastases from solid tumors, Approved February 2002

Drugs Approved in 2001

155. Campath; Berlex Laboratories; Injectable treatment of B-cell chronic lymphocytic leukemia, Approved May 2001
156. Femara (letrozole): Novartis; First-line treatment of postmenopausal women with locally advanced or metastatic breast cancer, Approved January 2001
157. Gleevec (imatinib mesylate): Novartis; Oral therapy for the treatment of chronic myeloid leukemia, Approved May 2001
158. Kytril (granisetron) solution; Roche; For the prevention of nausea and vomiting associated with cancer therapy, Approved June 2001
159. Trelstar LA (triptorelin pamoate): Debiopharm; Intramuscular injection for the treatment of advanced stage prostate cancer, Approved June 2001
160. Xeloda; Roche; Oral chemotherapy for the treatment of metastatic colorectal cancer, Approved May 2001
161. Zometa (zoledronic acid): Novartis; For the treatment of hypercalcemia of malignancy, Approved August 2001

Drugs Approved in 2000

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162. Mylotarg (gemtuzumab ozogamicin): Wyeth; For the treatment of CD33 positive acute myeloid leukemia (AML), Approved May 2000
163. Trelstar Depot (triptorelin pamoate): Debio Rechereche Pharmaceutique, Target Research Associates; For the palliative treatment of advanced prostate cancer, Approved June 2000
164. Trisenox (arsenic trioxide): Cell Therapeutics; For the induction of remission and consolidation in patients with acute promyelocytic leukemia (APL), Approved September 2000
165. Viadur (leuprolide acetate implant): Alza; For pain relief in men with advanced prostate cancer, Approved March 2000

Drugs Approved in 1999

166. Aromasin Tablets; Pharmacia & Upjohn; Exemestane Tablets, 25 mg, October 21, 1999
167. Busulflex; Orphan Medical; For use in combination for the treatment of leukemia, Approved February 1999
168. Doxil (doxorubicin HCl liposome injection): Alza; Treatment for ovarian cancer that is refractory to other first-line therapies, Approved June 1999
169. Ellence; Pharmacia & Upjohn; epirubicin hydrochloride, Approved September 1999
170. Ethyol (amifostine): US Bioscience, Alza; Treatment for xerostomia (dry mouth) due to radiation, Approved June 1999
171. Temodar; Schering-Plough; Treatment for refractory anaplastic astrocytoma, Approved August 1999
172. UVADEX Sterile Solution; Therakos; Treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL), Approved February 1999
173. **Zofran**; GlaxoSmithKline; Treatment for the prevention of chemotherapy and radiation-induced nausea, Approved January 1999

Drugs Approved in 1998

174. **Actiq**; Anesta Corporation; Treatment for Cancer Pain, Approved November 1998
175. **Anzemet**; Hoechst Marion Roussel; Treatment for the prevention of nausea and vomiting associated with chemotherapy and surgery, Approved February 1998
176. **Camptosar**; Pharmacia & Upjohn; Treatment for Colon or Rectal Cancer, Approved October 1998
177. **Gemzar** (gemcitabine HCL): Eli Lilly; Treatment for Lung Cancer, Approved August 1998
178. Herceptin; Genentech; Treatment for metastatic breast cancer, Approved October 1998

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– Kathopanisad

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179. Inform HER-2/neu breast cancer test; Oncor; Treatment for breast cancer prediction, Approved January 1998
180. **Neupogen:** Amgen; Treatment for slow white blood cell recovery following chemotherapy, Approval April 1998
181. Nolvadex; AstraZeneca; Treatment for Breast Cancer, Approved October 1998
182. **Photofrin**: QLT; Treatment for early-stage, microinvasive endobronchial non-small cell lung cancer, Approved January 1998
183. **Proleukin:** Chiron; Treatment for metastatic melanoma, Approved January 1998
184. Sclerosol Intrapleural Aerosol; Bryan Corporation; Treatment for malignant pleural effusions, Approved January 1998
185. **Valstar:** Anthra Pharmaceuticals; Treatment for Bladder Cancer, Approved October 1998
186. **Xeloda**: Roche; Treatment for advanced breast cancer tumors, Approved April 1998
187. **Zofran:** GlaxoSmithKline; Treatment for postoperative vomiting and nausea in adults, Approved April 1998

Drugs Approved in 1997

188. **Anzemet**: Hoechst Marion Roussel; Treatment for emesis, approved September 1997.
189. **Bromfenac**: Duract, Wyeth-Ayerst Laboratories; Management of acute pain, Approved July 1997.
190. **Femara** (letrozole): Novartis; Treatment for breast cancer, approved July 1997.
191. **Gliadel Wafer** (polifeprosan 20 with carmustine implant): Rhone-Poulenc Rorer, Guilford Pharmaceuticals; Treatment for brain cancer, approved February 1997.
192. **Intron A** (interferon alfa-2b, recombinant): Schering-Plough; Treatment for non-Hodgkin's lymphoma, Approved December 1997.
193. **Kytril** (granisetron) tablets; SmithKline Beecham; Prevention of nausea and vomiting associated with chemotherapy, approved November 1997.
194. **Lupron Depot** (leuprolide acetate for depot suspension): TAP Pharmaceuticals; Treatment for prostate cancer, approved July 1997.
195. Miraluma test; DuPont Merck Pharmaceutical Company; Test for breast cancer, Approved May 1997.
196. Neumega; Genetics Institute; Treatment for thrombocytopenia, Approved November 1997.
197. **Quadramet** (Samarium Sm 153 Lexidronam Injection): DuPont Merck Pharmaceutical Company; Treatment for pain associated with bone cancer, Approved March 1997.

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198. **Rituxan**: Biogen IDEC, Genentech; Treatment for non-hodgkin's lymphoma, Approved November 1997.
199. **Taxol**; Bristol-Myers Squibb; Treatment for AIDS-related Kaposi's Sarcoma, Approved August 1997.

Drugs Approved in 1996

200. Anexsia; Mallinckrodt Group; Treatment for chronic pain, Approved August 1996
201. Aredia (pamidronate disodium for injection): Chiron; Treatment for osteolytic bone metastases of breast cancer, Approved August 1996
202. **Arimidex** (anastrozole): AstraZeneca; Treatment for advanced breast cancer in postmenopausal women, Approved January 1996
203. **Campostar:** Pharmacia & Upjohn; Treatment for metastatic colorectal cancer, Approved June 1996
204. CEA-Scan; Immunomedics; Diagnostic imaging product for colorectal cancer, Approved April 1996
205. **Elliotts B Solution** (buffered intrathecal electrolyte/dextrose injection): Orphan Medical; Treatment of meningeal leukemia or lymphocytic lymphoma, Approved October 1996
206. **Eulexin** (flutamide): Schering-Plough; Treatment for prostate cancer, Approved June 1996
207. **Feridex I.V.**; Advanced Magnetics; Contrast agent for magnetic resonance imaging of liver lesions, Approved February 1996
208. **GastroMARK**; Advanced Magnetics; Contrast agent for magnetic resonance imaging of the gastrointestinal tract, Approved May 1996
209. **Gemzar** (gemcitabine HCL): Eli Lilly; Treatment for pancreatic cancer, Approved May 1996
210. Hycamtin (topotecan hydrochloride): SmithKline Beecham; Treatment for metastatic ovarian cancer, Approved May 1996
211. **Kadian**: Purepac Pharmaceutical; Treatment for chronic moderate to severe pain, Approved July 1996
212. **Leukine (sargramostim)**: Immunex; Treatment for the replenishment of white blood cells, Approved November 1996
213. **Lupron Depot** (leuprolide acetate for depot suspension): Abbott Laboratories; Treatment for advanced prostate cancer, approved January 1996
214. **Photodynamic Therapy**; Sanofi-aventis; Photodynamic therapy device for the treatment of esophageal cancer, Approved January, 1996

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215. **Taxotere** (Docetaxel): Rhone Poulenc Rorer; Treatment for locally advanced or metastatic breast cancer, Approved May 1996
216. UltraJect; Mallinckrodt Group; Treatment for chronic pain, Approved August 1996
217. **Visipaque** (iodixanol): Nycomed; Diagnostic contrast agent, Approved April 1996
218. **Zoladex** (10.8 mg goserelin acetate implant): AstraZeneca; Treatment for advanced prostate cancer, Approved January 1996

Drugs Approved in 1995

219. **Ethyol** (amifostine): Alza; Treatment to reduce renal toxicity associated with chemotherapy in subjects with advanced ovarian cancer, Approved December 8, 1995
220. **Intron A** (Interferon alfa-2b, recombinant): Schering-Plough; An adjuvant treatment to surgery in subjects at high risk for systemic recurrence of malignant melanoma, Approved December 1995
221. **Leukine** (sargramostim): Immunex; Treatment for mobilizing peripheral blood progenitor cells for use after transplantation., Approved on November 24, 1995
222. Self-examination breast pad; Inventive Products; Self-examination breast pad, Approved on December 22, 1995

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Issue 161

5118 Kali Era, 2074 Vikramarka Era, 1938 Salivahana Era
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REFERENCES AND NOTES[17]

[1] Dr. Rao Vepachedu is a registered patent attorney with extensive experience in the management of intellectual property and extensive experience in research and teaching. He currently works for Cardinal Intellectual Property (CIP), Cardinal Risk Management (CRM), and Cardinal Law Group (CLG). In addition, he is the president of Vepachedu Educational Foundation Inc. (www.vepachedu.org), a 501(c) (3) educational foundation. For more information visit:
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[2] Phases of Clinical Trials http://www.cancer.net/research-and-advocacy/clinical-trials/phases-clinical-trials
About Clinical Trials http://www.cancer.net/research-and-advocacy/clinical-trials/about-clinical-trials;
http://www.cancer.net/sites/cancer.net/files/phases_of_clinical_trials.pdf
Drug Approval and Labeling http://www.cancer.net/research-and-advocacy/introduction-cancer-research/drug-approval-and-labeling
[3] Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review
https://www.fda.gov/forpatients/approvals/fast/ucm20041766.htm
[4] Patients For Affordable Drugs http://www.patientsforaffordabledrugs.org/about/
[5] The Constitution of the United States gives Congress the power to enact laws relating to patents, in Article I, section 8, which reads "Congress shall have power . . . to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." For more see https://www.uspto.gov/sites/default/files/inventors/edu-inf/BasicPatentGuide.pdf
[6] Cancer Moonshot Challenge https://www.uspto.gov/about-us/national-cancer-moonshot
Cancer Moonshot Awards https://www.youtube.com/watch?v=bBnV_gVx-Ec
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[15] 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.
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"Where the mind is without fear and the head is held high, Where knowledge is free Where the world has not been broken up into fragments, By narrow domestic walls." Rabindranath Tagore (1861-1941), Gitanjali, 1912.

One World One Family
AUM! SWASTI!
Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih! (Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)
SWASTI! AUM!

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