

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

May the golden-eyed Savitar come hither!
Steering forth he rises from the lap of the dawn!
Praised by singers, my God Savitar!
Stopped 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!
- Kathopanishad

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Issue 166

Chief Editor: డాక్టర్ శ్రీనివాసరావు వేపచేదు | डॉक्टर श्रीनिवासरावु वेपचेदु | [Dr. Sreenivasarao Vepachedu](#)

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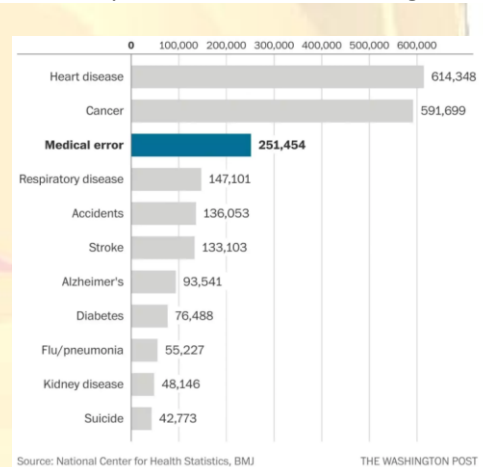
AMGEN V. EXCIVA¹

Ensuring appropriate medication use is a complex process involving multiple organizations and professionals from various disciplines.

Experts estimated that as many as 98,000 people die in any given year from medical errors that occur in hospitals. That's more than that die from motor vehicle accidents, breast cancer, or AIDS--three causes that receive far more public attention. Indeed, more people die annually from medication errors than from workplace injuries. Medical errors now third leading cause of death in United States, claiming 251,000 lives every year, more than respiratory disease, accidents, stroke and Alzheimer's². Add the financial cost to the human tragedy, and medical error easily rises to the top ranks of urgent, widespread public problems.

If these findings are generalizable, the increased hospital costs alone of preventable adverse drug events affecting inpatients are about \$2 billion for the nation as a whole. Medication errors occur frequently in hospitals. But, hospital patients represent only a fraction of the total population at risk of experiencing a medication-related error. In 1998, nearly **2.5 billion prescriptions were dispensed by US pharmacies at a cost of about \$92 billion**. One study found that between three and 11 percent of hospital admissions were attributable to adverse drug events (ADEs). Children are at particular risk of such medication errors. Many errors go undocumented and unreported and the most common causes of potentially preventable ADEs, such as cardiac arrests, were medication errors and toxic effects. Some errors are errors of commission, e.g., administration of an improper drug, while others are errors of omission, e.g., failure to administer a drug that was prescribed.

In addition to the unfortunate health consequences suffered by many as a result of medical error, there are direct and indirect costs borne by society as a whole as a result of medical errors. Direct costs refer to higher health care expenditures, while indirect costs include factors such as lost productivity, disability costs, and personal costs of care. The estimated national cost of ADEs was \$37.6 billion (of which preventable ADE cost was \$17 billion), approximately 4% of national health expenditures in 1996 (*To Err*



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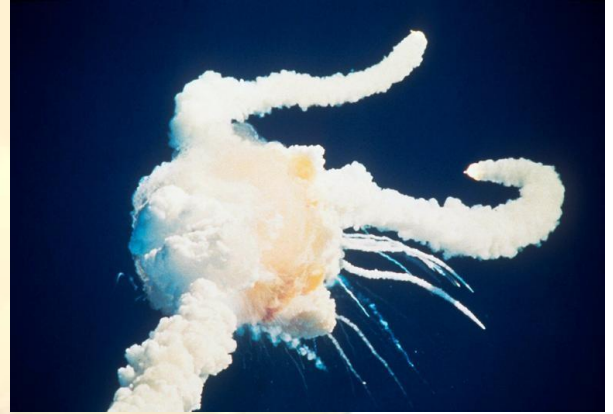
is Human: Building a Safer Health System. [Institute of Medicine, Committee on Quality of Health Care in America. Read at NCBI Bookshelf³](#).

Media coverage has been limited to occasional reporting of anecdotal cases, while focused on useless gossip and punditry on salacious political and sexual scandals and alien bashing for our (American) addiction to guns and drugs for ratings. Three Mile Island or the *Challenger* accident, Florida School Shooting, Boston Marathon Bombing, Timothy McVey's Bombing of Federal Building, 9-11 Towers, grab people's attention and make the front page of newspapers, unless it is Betsy Lehman (died from an overdose during chemotherapy), Willie King (who had the wrong leg amputated) or Michael Jackson (died due to the drug overdose of cocktail of drugs propofol, lorazepam, and midazolam).



The impact of anecdotal information on safety may also be less effective in health care than in the nuclear waste or airline

industries, where an individual event often impacts dozens or hundreds of people at a time, making everybody to stop flying and start crying. [The most common American initial reaction is to find a scapegoat to blame, demonize, and destroy; mostly aliens like the American MS13, Qadafis and Husains without Weapons of Mass Destruction \(because if they had they would have destroyed America and Isreal, and the wise would say prevention is better than cure, a stitch in time saves nine, and so on\); "Russians with Internet and Facebook meddling in our internal affairs of personal emails, money laundering, and GMO crops"; "North Koreans with nuukkuulaar duds aimed at US"; "Iranians with natural gas to serve Russians"; "Syrians with natural gas pipelines from Iran rather than from Qatar to serve Russians"; and Socialism with Single Payer System; etc.- even when an error did not occur.](#)



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However, most often, even apparently single events or errors are due to the convergence of multiple contributing factors. Blaming an individual does not change these factors and the same error is likely to recur, e.g., [Virginia Tech School Shooting](#), [Sandy Hook School Shooting](#), [San Bernardino School Shooting](#), [Florida School Shooting](#), [Virginia Tech School Shooting](#), [Kentucky Scholl Shooting](#), [291 School Shootings In America Since 2013](#). Preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors.



[CENTER FOR DRUG EVALUATION AND RESEARCH NDA 125320/S-007](#)

APPROVAL PACKAGE

- 04/27/2012 SUPPL-54 [Label](#); 09/14/2012 SUPPL-85 [Label](#);
- 02/15/2013 SUPPL-80 [Label](#); 06/13/2013 SUPPL-94 [Label](#);
- 08/23/2013 SUPPL-114 [Label](#); 08/23/2013 SUPPL-124 [Label](#);
- 06/04/2014 SUPPL-155 [Label](#); 12/05/2014 SUPPL-160 [Label](#);
- 06/08/2015 SUPPL-168 [Label](#)/ [Letter](#);
- 03/02/2016 SUPPL-177 [Label](#)/ [Letter](#);
- 01/04/2018 SUPPL-182 [Label](#)/ [Letter](#);
- 01/24/2018 SUPPL-185 [Label](#)/ [Letter](#)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 125320/S-007

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Proprietary Name Review(s)	X
Other Review(s)	X
Administrative/Correspondence Document(s)	X

[BLA 125320 PROLIA \(denosumab\) Injection, 60 mg/mL Amgen, Inc.](#)

The Proprietary Name Risk Assessment findings indicate that the proposed name, Prolia, is not vulnerable to name confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Prolia, for this product at this time.

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[Phonetic and Orthographic Computer Analysis \(POCA\) program](#) is a software tool that uses an advanced algorithm to determine the orthographic and phonetic similarity between two drug names. The program can compare a drug name against multiple drug names found in several different "data sources" contained in the software. The two data sources provided through this download are [Drugs@FDA](#)⁴ and [RxNorm](#)⁵.

Within the Center for Drug Evaluation and Research (CDER), the Division of Medication Error Prevention and Analysis (DMEPA) reviews medication error reports on marketed human drugs including prescription drugs, generic drugs, and over-the-counter drugs. DMEPA uses the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) definition of a medication error. Specifically, a medication error is "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

DMEPA includes a medication error prevention program staffed with healthcare professionals. Among their many duties, program staff review medication error reports sent to MedWatch, evaluate causality, and analyze the data to provide solutions to reduce the risk of medication errors to industry and others at FDA. Additionally, DMEPA prospectively reviews proprietary names, labeling, packaging, and product design prior to drug approval to help prevent medication errors. Although DMEPA encourages manufacturers to perform their due diligence when naming their drug products and we strive to avoid approving confusing proprietary names for drug products, there are cases of adverse events where a name of a marketed product is identified as a source of confusion and error. Therefore, we continue to encourage healthcare providers, patients and consumers to report all medication errors to MedWatch so that we can be made aware of potential problems related to drug names and the Agency can provide effective interventions that will minimize further errors. In some situations, changing a proprietary name while the product is marketed may be necessary to address safety issues resulting from the name confusion errors.

INDICATIONS AND USAGE
Xgeva is a RANK ligand (RANKL) inhibitor indicated for:

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. (1.1)
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. (1.2, 14.3)
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. (1.3)

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DMEPA also works closely with federal partners, patient safety organizations such as Institute for Safe Medication Practices (ISMP), standard setting organizations such as the United States Pharmacopeia (USP), and foreign regulators to address broader product safety issues. FDA and the Institute for Safe Medication Practices (ISMP) have launched a national education campaign to eliminate the use of ambiguous medical names and abbreviations that are frequently misinterpreted and lead to mistakes that result in patient harm.

Safety Considerations for Product Design to Minimize Medication Errors Guidance for Industry⁶: Error prevention in manufacturing is not a new concept. Corrective and Preventive Action, Change Control, and Quality Risk Management are well-recognized elements of current good manufacturing practice (CGMP) for drug products that focus on investigating, understanding, and correcting identified risks and managing the changes necessary for correction to prevent their recurrence while preventing unintended consequences. The same principles can be applied to the overall design of a drug product to identify and eliminate design features that may contribute to medication errors.

Drug product design features that predispose end users to medication errors may not always be overcome by product labeling or health care provider or patient¹⁵ education. Therefore, it is preferable to eliminate, or at least minimize to the extent possible, these hazards from the product design. It is not possible to predict all medication errors. However, medication errors can be minimized by conducting **premarketing risk assessments to evaluate how users will interact with the drug product within various environments of use within the medication use system** using well-established human factors engineering analytical methods.

The FDA expects manufacturers to consider the use of these analytical methods when developing drug products to build safety into drug product throughout its lifecycle and to identify those safety characteristics of the product that they consider to be critical. In 2000, the Institute of Medicine (IOM) published a report entitled *To Err Is Human: Building a Safer Health System* (Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Institute of Medicine, National Academies Press: Washington DC, November 1999)⁷, stating that up to 98,000 deaths occur yearly due to medical errors, making medical errors the eighth leading cause of death in the United States. The IOM cited labeling and packaging issues as the cause of 33 percent of medication errors and 30 percent of fatalities from medication errors. **Seven thousand (7,000) deaths annually were attributed to medication errors.**

On September 27, 2007, the reauthorization and expansion of the Prescription Drug User Fee Act (PDUFA IV) was signed into law as part of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law

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110-85) committing FDA to implement measures to reduce medication errors related to look-alike and sound-alike proprietary names - one of the many goals of the FDA.



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IMMIGRATION UPDATE

The United States Citizenship and Immigration Services (USCIS) has been accepting credit card payments for naturalization, renewal, and replacing the Green Cards⁸ when filed online and for naturalization forms filed at Lockbox facilities since 2015. The USCIS expanded the acceptance of credit card payments for filing 41 fee-based forms processed at USCIS Lockbox facilities, by Visa, MasterCard, American Express or Discover using Form G-1450, Authorization for Credit Card Transaction (PDF, 252 KB) on 14 February 2018. The USCIS will enter credit card data into the Pay.gov system, operated by the US Department of the Treasury, and destroy the Form G-1450.

On February 16th, the USCIS announced that would no longer accept power of attorney signatures, effective 18 March 2018⁹. An applicant or petitioner must sign his or her benefit request. However, a parent or legal guardian may sign for a person who is less than 14 years old. A legal guardian may sign for a mentally incompetent person. By signing the benefit request, the applicant or petitioner, or parent or guardian certifies under penalty of perjury that the benefit request, and all evidence submitted with it, either at the time of filing or thereafter, is true and correct. Unless otherwise specified in this chapter, an acceptable signature on a benefit request that is being filed with the USCIS is one that is either handwritten or, for benefit requests filed electronically as permitted by the instructions to the form, in electronic format¹⁰.

The USCIS warns that it may receive more H-2B nonimmigrant worker petitions than the 33,000 H-2B visas available in the second half of Fiscal Year 2018 due to an unprecedented number of applications. The US Department of Labor announced that it would not begin releasing H-2B temporary labor certifications until 20 February 2018. The final receipt date for the 33,000 H-2B worker petitions when the petitions reached the limit was 15 December 2017 for requesting employment having start dates before 1 April 2018.

PATENT LAW UPDATE

CAMBODIA (KH): The European Patent Office (EPO) and Cambodia entered into a Validation Agreement¹¹, effective 1 March 2018¹², allowing validation by Cambodia in its territories, and applicants to designate Cambodia for validation of a patent granted from a European patent application filed in the EPO, excluding pharmaceutical inventions due to a World Trade Organization (WTO)'s waiver to IP rights on pharmaceutical products until 2033 applicable to Least Developed Countries (LDCs). The validation fee EUR 180 must be paid to the EPO within six months of the date on which the European Patent Bulletin mentions the publication of the European search

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report, or, where applicable, within the period for performing the acts required for an international application's entry into the European phase.

The European Validation System creates opportunities to patent applicants seeking protection outside Europe without going through the process of national application and prosecution, extending the European reach into non-European countries and territories, reducing costs to mostly multi-national corporations that need patent protection extended beyond the EU. However, the National and European filing routes coexist, while the enforcement of the patent will under the national IP laws and regulations of the validating country. So far, EPO has already established such validation agreements with a few non Western European countries such as Morocco (01.03.2015, Africa), Moldova (01.11.2015, Eastern Europe) and Tunisia (01.12.2017, Africa). Angola, Brunei Darussalam, Georgia, Laos, and the African Organization for Intellectual Property (OAPI) are hoping to join the club.

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REFERENCES AND NOTES¹³

¹ Registration No. 3921172 <http://tsdr.uspto.gov/caseviewer/pdf?caselid=87195766&docIndex=0&searchprefix=sn#docIndex=0>

EXHIBIT 1: Aggressive trademark litigation tactics aka the trademark bullying is “the practice of a trademark holder using litigation tactics in an attempt to enforce trademark rights beyond a reasonable interpretation of the scope of the rights granted to the trademark holder” Trademark Litigation Tactics and Federal Government Services to Protect Trademarks and Prevent Counterfeiting, REPORT TO CONGRESS, April 2011, Pursuant to Public Law 111-146, a bill which made technical amendments to the Lanham Act, USPTO with DOC/IPEC authored this report and submitted to Hill on April 27, 2011 <https://www.uspto.gov/sites/default/files/trademarks/notices/TrademarkLitigationStudy.pdf>

EXHIBIT 2: Center For Drug Evaluation And Research; Approval Package for: APPLICATION NUMBER: BLA 125320/S-007

EXHIBIT 3: Vowels, Consonants, and Words in the English language <https://en.oxforddictionaries.com/explore/how-many-words-are-there-in-the-english-language>

EXHIBIT 4: Pharm Exec's Top 50 Companies 2017 (<http://www.pharmexec.com/pharm-execs-top-50-companies-2017>)

EXHIBIT 5: Merck sells the pharmaceutical product EXXIV (etoricoxib)

EXHIBIT 6: ViiV sells LEXIVA® (fosamprenavir calcium)

EXHIBIT 7: NUTIVA sells the product SUGIVA

EXHIBIT 8: STIEFEL LABORATORIES sells the pharmaceutical product EXTINA (ketoconazole)

EXHIBIT 9: CEVA sells the pharmaceutical products CEVA STIM, CEVA ZURIL (toltrazuril), and CEVA VALORA. CEVA ANNUAL REPORT 2016

<https://www.ceva.com/en/News-Media/Annual-reports/2016-Annual-Report>

EXHIBIT 10: Evonik Degussa GmbH (EVONIK) sells REXIVA

EXHIBIT 11: XIGEN SA owns XIGEN®

EXHIBIT 12: P-EXEVA (PAROXETINE MESYLATE, <http://www.pexeva.com/>)

EXHIBIT 13: GSK sells ABR-EVA (DOCOSANOL);

EXHIBIT 14: Lundbeck sells CARN-EXIV (CARBAMAZEPINE)

EXHIBIT 15: Merck sells CRI-XIVA-N (INDINAVIR SULFATE) http://www.merck.com/product/usa/pi_circulars/c/crixivan/crixivan_pi.pdf

EXHIBIT 16: N EXGE N PHARMA

EXHIBIT 17: Roche/GENENTECH sells TAR-CEVA (ERLOTINIB HYDROCHLORIDE) <http://medsafe.govt.nz/profs/Datasheet/t/tarcevatab.pdf>

EXHIBIT 18: APPLICATION NUMBER: NDA 125320/S-007, November, 18, 2010 Indications: XGEVA® is a RANK ligand (RANKL) inhibitor indicated for “Prevention of skeletal-related events in patients with bone metastases from solid tumors”

EXHIBIT 19: Amgen failed to procure the Proprietary Name Risk Assessment for XGEVA

EXHIBIT 20: ViiV proposal to EXCIVATM-UG-TDR

EXHIBIT 21: EXCIVATM-UG-TDR indicated willingness to consider ViiV proposal

EXHIBIT 22: Communications With Amgen Counsels

EXHIBIT 23: EXCIVATM-UG-TDR’s counsel indicated willingness to consider an amendment if proposed in good faith, to which Amgen never responded

EXHIBIT 24: The FDA/CDER/CDER guidance

EXHIBIT 25: PROPRIETARY NAME REVIEW-PROLIA®

² Medical errors now third leading cause of death in United States

³ To Err is Human: Building a Safer Health System. Institute of Medicine, Committee on Quality of Health Care in America. Read at NCBI Bookshelf

⁴ Drugs@FDA

⁵ RxNorm

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⁶ Safety Considerations for Product Design to Minimize Medication Errors Guidance for Industry

⁷ In 2000, the Institute of Medicine (IOM) published a report entitled *To Err Is Human: Building a Safer Health System* (Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Institute of Medicine, National Academies Press: Washington DC, November 1999)

⁸ Renewal, and replacing the Green Cards

⁹ The USCIS announced that would no longer accept power of attorney signatures, effective 18 March 2018.

¹⁰ <https://www.uscis.gov/sites/default/files/USCIS/Laws/Memoranda/2018/2018-02-16-PM-602-0134.1-Signatures-on-Paper-Applications-Petitions-Requests-and-Other-Documents.pdf>

¹¹ On 23 January 2017, the President of the European Patent Office and the Cambodian Minister of Industry and Handcraft signed an agreement on the validation of European patents (validation agreement). On 24 November 2017, the King of Cambodia promulgated the Royal Kram N°NS/RKM/1117/017 on the ratification of the agreement on validation of European patents between the Government of the Kingdom of Cambodia and the European Patent Organisation. On 8 December 2017, a declaration (Prakas) N°282 MIH/2017 was adopted on the Regulation and Procedures for the validation of European Patents in Cambodia. The adoption of this legislation has created the legal basis necessary for the validation system to operate. <https://www.epo.org/law-practice/legal-texts/official-journal/2018/02/a16.html>; <https://www.epo.org/law-practice/legal-texts/official-journal/2018/02/a16/2018-a16.pdf>

¹² On 23 January 2017, the President of the European Patent Office and the Cambodian Minister of Industry and Handcraft signed an agreement on the validation of European patents (validation agreement). On 24 November 2017, the King of Cambodia promulgated the Royal Kram N°NS/RKM/1117/017 on the ratification of the agreement on validation of European patents between the Government of the Kingdom of Cambodia and the European Patent Organisation. On 8 December 2017, a declaration (Prakas) N°282 MIH/2017 was adopted on the Regulation and Procedures for the validation of European Patents in Cambodia. The adoption of this legislation has created the legal basis necessary for the validation system to operate. <https://www.epo.org/law-practice/legal-texts/official-journal/2018/02/a16.html>; <https://www.epo.org/law-practice/legal-texts/official-journal/2018/02/a16/2018-a16.pdf>

¹³ In addition to the primary sources cited above, additional references include:

New York Times, Washington Post, Mercury News, Bayarea.com, Deccan Chronicle, the Hindu, Hindustan Times, Times of India, AP, Reuters, AFP, The Guardian, Pravda, Spiegel, Connexion, etc.

"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 Sadqamaya, 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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