SafeDrugNames.com

Preventing Patient Harm and Predicting FDA Behavior

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Overview

- Why Use Computerized Search to Screen Pharmaceutical Trademarks?
- Register the Trademark
- Prevent Medication Errors and Patient Harm
- Anticipate and Respond to FDA Naming Decisions

Why Use Computerized Search to Screen Pharmaceutical Trademarks?

- Computers can measure similarity objectively (although imperfectly)
- Computers can quickly scan huge databases
- Some software combines search with collaboration and document management applications
- Regulatory agencies use the software, so trademark owners are forced to do the same

Registering the Trademark

- Use computerized search to clear a mark prior to legal registration
- Consider likelihood of confusion, class of trade, likelihood of harm, etc.
- Attempt to avoid infringement and dilution problems
- Lawyers are the relevant experts

Prevent Medication Errors and Patient Harm

- Wrong Drug Errors
  - 0.13% of all outpatient prescriptions
  - 3.9 million/year based on 3 billion prescriptions dispensed annually
  - 6.5% (253,500) are clinically significant
  - See Flynn, et al. J Am Pharm Assoc. 2003 Mar-Apr;43(2):191-200
- Many causes
  - Noisy and degraded stimuli
    - Bad handwriting
    - Bad fax/printout
    - Noisy cell phones, answering machines, work areas
  - Distractions
    - Ringing phones
    - Other conversations
    - Waiting patients
    - Muzac

Prevent Medication Errors and Patient Harm

- Many Causes of Wrong Drug Errors
  - Lack of distinguishing info on prescription
    - Indication/reason for use
  - Slow adoption of bar codes, computerized order entry
  - Bad computer interfaces
  - Similarity between names
  - Frequency differences between names

Prevent Medication Errors and Patient Harm

- Harm = probability of error * num. opportunities for error * probability of failing to catch the error before it reaches the patient * severity of the consequences of each error
- Very difficult to predict the severity of the consequences of each error
  - How long exposed to the wrong drug/without the intended drug?
  - How essential was the intended drug/toxic was the wrong drug?
  - How resilient/vulnerable is the patient?

Prevent Medication Errors and Patient Harm

- Harm prevention is the greatest ethical responsibility
- Harm prevention has high value in preventing future personal injury liability
- The FDA and other regulators presumably focus a lot on harm

Prevent Medication Errors and Patient Harm

- The similarity measures used in SafeDrugNames.com have been validated in a series of peer reviewed publications
- These measures are correlated with the probability of error in short term memory and visual perception
- You can benchmark your search results against the experimental data
- Still no guarantees
  - Even “confusing” names will be correctly dispensed most of the time
  - Sometimes “non-confusing” names will be involved in wrong drug errors

Anticipate and Respond to FDA Naming Decisions

- FDA, POCA, and Trademark Roulette
- What is POCA?
- What would it take to make the FDA process predictable?
- How Can SafeDrugNames.com help an applicant organization prepare for FDA name review and respond to negative decisions?

FDA, POCA, and Trademark Roulette

- FDA process still unpredictable and not transparent
- One third of proposed names still being rejected
- Guidance on good naming practices still not forthcoming
- POCA being used internally but not available externally
- Uncertainty about POCA “spreading” to other jurisdictions

What Is POCA?

- A computer program for doing similarity searches in drug product databases
- Designed and implemented by Project Performance Corporation under contract to FDA
  - Key Scientists
    - Greg Kondrak
    - Bonnie Dorr

What is POCA

- Relevant publications
  - Kolatch, Erica, Jessica Toye, and Bonnie Dorr. "Look Alike / Sound Alike Algorithms for Assessing Drug Name Similarities", Project Performance Corporation TR, McLean, VA, 2004
  - Kondrak, Grzegorz, and Bonnie J. Dorr, "Identification of Confusable Drug Names: A New Approach and Evaluation Methodology", **submitted** to *Journal of AI in Medicine*, 2005.
  - Kondrak, Grzegorz and Bonnie J. Dorr, "Identification of Confusable Drug Names: A New Approach and Evaluation Methodology", in *Proceedings of COLING*, Geneva, Switzerland, 2004.
  - G. Kondrak. *A New Algorithm for the Alignment of Phonetic Sequences.* Proceedings of the First Meeting of the North American Chapter of the Association for Computational Linguistics (ANLP-NAACL 2000), pp. 288-295, Seattle, April, 2000.

What is POCA?

- Key Presentations
  - Health Canada Presentation
  - June 2003 FDA presentation
  - December 2003 FDA presentation

What is POCA?

- Orthographic similarity
  - N-Gram, edit distance, longest common subsequence, BiSim, etc.
- Phonetic/Phonological similarity
  - ALINE (based on Kondrak's thesis)
- Non-name attribute similarity
  - Discussed but never publicly demonstrated
- Document management and collaboration features

How Good Is POCA?

- Pretty good, but difficult to tell for sure
- Previously cited publications give some evaluation data, based on ability to reproduce USP error pairs
- Algorithms and parameter settings not all available to the public
- Too little is known about how POCA handles non-name attributes

How to Make POCA Predictable

- Specify, in advance, a search procedure
  - Which similarity measures will be used?
  - Which parameter settings?
  - How will non-name attributes (e.g., strength, dosage form, route of administration) be handled
- Specify a database
  - Orange Book, USPTO (class 5), Multum Lexicon, IMS Trademarks In Use, international databases
- Specify a similarity threshold
- Specify a harm threshold and/or a standard procedure for assessing harm
- Make POCA publicly available

Problems with POCA

- Lack of FDA expertise in computer science, trademark law, psycholinguistics, or human factors
- Process not stable or transparent
- Not available to the public for use or research
- Uncertainty about handling of non-name attributes
- Does not deal with effects of prescribing frequency

Using SafeDrugNames.com to Anticipate to FDA

- To the extent possible, replicate POCA search results before submitting a name for approval
  - Use same orthographic measures on same database (e.g., Orange Book)
  - Our approach to phonetic search is similar but not identical.
  - Kondrak has not released specific parameter settings for ALINE algorithm

Using SafeDrugNames.com to Respond to FDA

- Compare scores for rejected name to published benchmarks from experimental data
- Compare scores for rejected name to distribution of all possible pairwise similarity scores
- Compare scores for rejected name to scores for previously approved and rejected names

Who is Pharm I.R., Inc.

- Bruce Lambert, Ph.D., Department of Pharmacy Administration, University of Illinois at Chicago College of Pharmacy
- Clement Yu, Ph.D., Department of Computer Science, UIC
- King Lup Liu, Ph.D., free lance programmer

How Else Can Pharm I. R., Inc. Help?

- We can help you understand what POCA is and how it works
- We can help you critique POCA's weaknesses
- We can develop custom software solutions to improve the quality of drug product searching
- We can offer expert opinion about search strategies and search results
- We can assist in the development of new methods for evaluating proposed drug names (i.e., good naming practices)

Proposed Experiments

- Database comparisons
  - Compare Orange Book, Multum, USPTO, IMS Trademarks in Use
  - Look at number of names, overlap, availability of other attributes, etc.
- Compare computerized search to existing processes in Lilly
- Compare SafeDrugNames to POCA
- Compare computerized search to results of perception and memory experiments

Interactive Demonstration

- SafeDrugNames.com
- Thank you