

Does Restricting Use Of Prescriber Data Achieve Appropriate Policy Goals?

Donna A. Boswell

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Top Policy Goal -- Safe and Effective Medicines

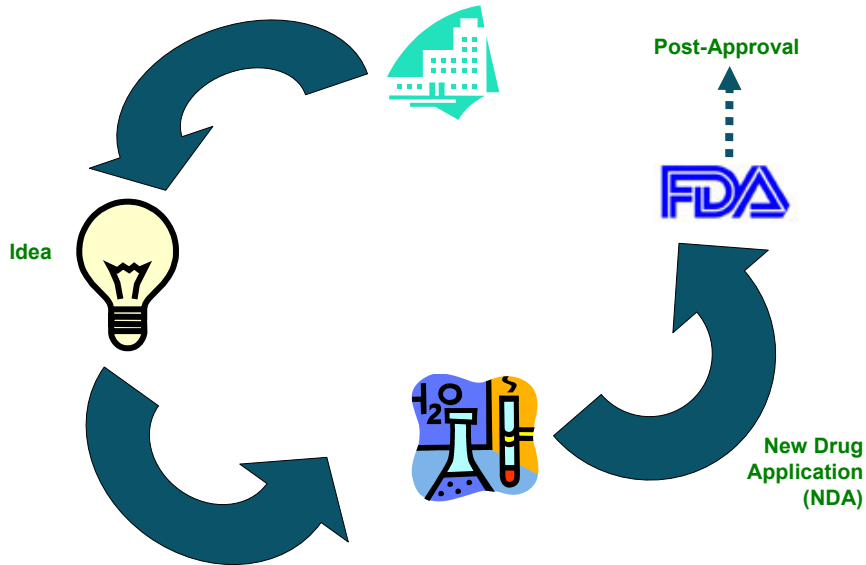


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Drug Development and Regulation

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Post Approval Safety --
**FDA's Expectations Regarding
A Manufacturer's Post-Approval Role
In Assuring Safe and Effective Medicines
Depends Heavily on Manufacturer-
Prescriber Communication**



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FDA Review

- FDA

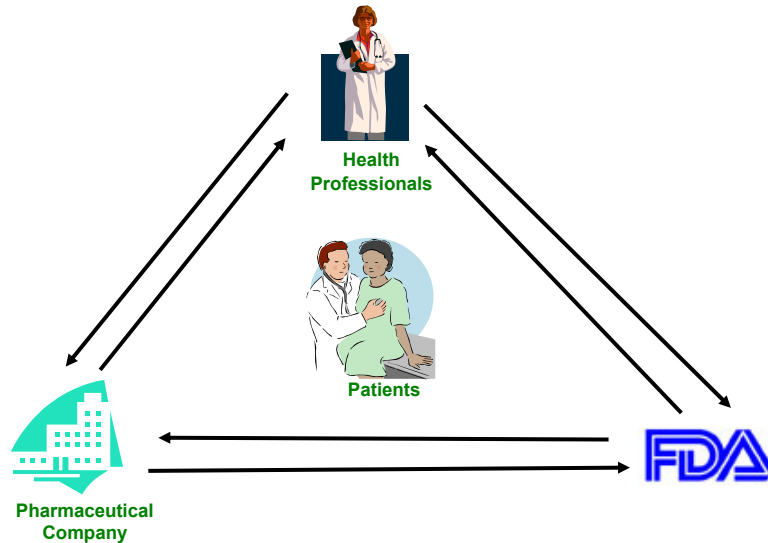
- Evaluates preclinical and clinical data
- Makes a critical judgment on whether the drug is safe and effective for each proposed use
- Revises and approves detailed labeling
- Seeks agreement on, or may require, any other conditions needed to assure that the drug will be used safely and effectively for its approved uses



Risk Minimization Action Plans (RiskMAPs) and Restricted Distribution

- Targeted education and outreach
- Active monitoring of prescribing and usage
- Performance-linked access systems (e.g., “no blood, no drug”)
- Active adverse event (AE) surveillance through frequent prescribers
- Patient and physician registries

Communication



Emerging Safety Issue

- **Example: Company obtains new information about potential liver toxicity risk that may be associated with its drug**
- **Use of prescriber data: *Targeted* education and outreach**
 - Inform prescribers about potential risk and need to conduct periodic liver function testing
 - Follow-up with prescribers
 - Determine whether liver function testing is being done
 - Provide educational program for prescribers who are not conducting liver function testing
 - Solicit information on liver toxicity-related adverse events

Misuse and Diversion

- **Example: Oxycontin (oxycodone hydrochloride)**
 - Pain relief drug is critical to cancer patients, but poses high risk of abuse, diversion, and misuse
- **Use of prescriber data: targeted education and outreach**
 - Identify prescribers who need additional education (and provide the education)
 - Provide addiction treatment referrals
 - Involve law enforcement authorities
- **Use of prescriber data: active monitoring**
 - RiskMAP requires sponsor to evaluate information from various databases to assess drug exposure
 - Can be used to identify health professionals who are prescribing an inappropriately high volume

Dangerous Drug-Drug Interaction

- **Example: Symlin (pramlintide acetate)**
 - Provides important benefit to people with diabetes
 - But there is an increased risk of hypoglycemia if the drug is mixed with insulin (e.g., if a patient uses the same syringe)
- **Use of prescriber data: active monitoring**
 - RiskMAP requires sponsor to introduce product into the marketplace gradually, with concomitant evaluation of patterns of product use by “targeted” and “non-targeted” health care providers
 - Targeted physicians include those who specialize in diabetes management and are supported by diabetes educators
 - “You will assess available databases for information regarding Symlin prescription practices and submit the results of these assessments on a semiannual basis” (FDA Approval Letter, March 16, 2005)

Special Training and Restrictions

- **Example: Accutane (isotretinoin)**
 - Drug for severe skin condition is known to cause birth defects
- **Performance-Linked Access System**
 - Only health professionals with sufficient knowledge and training, and who have agreed to manage patients in accordance with certain standards, can prescribe the drug
- **Use of prescriber data: active monitoring**
 - Ensure that only health professionals who are part of the access system are prescribing the drug
 - Identify additional health professionals with patients who might benefit from the drug

Drug Safety and Access

- Risk management for numerous breakthrough medicines is dependent upon prescriber data
- Prescriber data can play a constructive role in
 - *making new drugs available to patients*
 - *managing emerging safety risks*
 - *Informing active prescribers about new labeling, including new pediatric data, new geriatric data, and safer dosing regimens*
- Prescriber data will play an increasing role with the emergence of personalized medicine and pharmacogenomics

The New Hampshire Statute

- “Records relative to prescription information containing patient-identifiable and *prescriber-identifiable data* shall not be licensed, transferred, used, or sold . . . for any commercial purpose, except for the limited purposes of
 - Pharmacy reimbursement
 - Formulary compliance
 - Care management
 - Utilization review by a health care provider, the patient’s insurance provider or the agent of either
 - Health care research
 - Or as otherwise provided by law”
- NH Stat. 318:47-f (June 2006) (emphasis added)

The New Hampshire Statute

- “Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to
 - influence sales or market share of a pharmaceutical product,
 - influence or evaluate the prescribing behavior of an individual health care professional, or
 - evaluate the effectiveness of a professional pharmaceutical detailing force.”

Legislative Intent

- Reinforce patient privacy (but this is not in dispute; is not at risk; is not enhanced by NH law)
- Create a physician/prescriber right of privacy?
- Cost-containment?
 - *“In restricting the commercial use of identity data, doctors will be allowed to make prescribing decisions based on therapeutic value without influence from drug reps. This can lead to slower increases in cost for Medicaid and health insurance premiums paid by businesses and individuals.” [NH House Committee on Health, Human Services and Elderly Affairs (Feb 2006)]*
 - But all other cost-containment tools attempt to modify prescriber behavior, not just leave them free...
 - Is this another way of saying that the real policy goal is to prohibit marketing?

Legal Challenge

- IMS and Verispan successfully challenged the statute in federal court
- *IMS Health Inc. v. Ayotte* (June 30, 2007)
 - State has no substantial government interest in protecting prescriber privacy
 - Prescribers are not “vulnerable victims”; rather, they are highly trained professionals able to evaluate marketing messages
 - The data are not being used to compromise patient privacy
 - Restrictions on prescribing information do not directly advance the State’s interest in protecting public health and containing health care costs
 - There are less restrictive means of address the State’s underlying concerns
 - If concern is that detailing should not go unrebuted, the State could provide or facilitate the provision of competing information that will help prescribers balance and place in context the sales messages provided by detailers
 - *E.g.*, providing “best practice” guidelines and requiring participation in continuing medical education
 - If concern is that detailing drives up Medicaid costs, the State could ensure that it rejects requests to prescribe drugs that are not medically necessary, and take cost considerations into account when deciding which drugs should be provided only upon prior authorization

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