

FDA Reporting

- Adverse reactions that occur only rarely (e.g., 1 out of a million) often will not be detected until after a drug is approved and used in millions of people.
- Therefore, the FDA relies on postmarketing information to establish a better understanding of adverse events.
- Historically, drugs have been approved by the FDA only to be withdrawn from the market due to postmarketing adverse events, either voluntarily by the manufacturer or because of mandate from the FDA.
- Pharmaceutical companies are required by the FDA to submit quarterly reports of all ADRs for the first 3 years that a drug is on the market as part of the postmarketing surveillance system.



Fda Report Adverse Reaction To Drugs

G Thomas



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