90 Crown Street, New Haven CT 06510

Dear Health Educators,

We hope you find all of the materials in the *Breaking News About "B"* teaching kit helpful and informative for your students. While the recommended activities do not discuss treatment options, we wanted to take a moment to remind you about the importance of sharing any product safety information that might come from your students or others.

Product safety monitoring is important so that drug manufacturers are able to identify any trends in the performance and quality of their products that may require corrective or preventative action before they adversely affect the safety of patients.

Please use the reference aid on the back of this letter to help identify any adverse events. If you become aware of any product safety report as described in this reference aid, promptly forward all available information to Young Minds Inspired (YMI) at 1-800-859-8005 or by email to feedback@ymiclassroom.com.

Thank you,

Dominic Kinsley
Managing Partner/Editor in Chief
Young Minds Inspired (YMI)

Safety Reporting Reference Aid for Health Care Educators

Young Minds Inspired
Breaking News About "B"

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Adverse Events

An adverse event is any untoward medical occurrence in a patient or consumer administered a pharmaceutical or over the counter product.

All reports of adverse events should be forwarded, regardless of the seriousness of the event, whether or not there is a causal relationship with the pharmaceutical or over the counter product, and regardless of whether the event is mentioned in the product label/instructions.

Adverse events include but are not limited to:

- *abnormal test findings*
- *clinical symptoms and signs and/or new diagnoses*
- *progression/worsening of underlying disease*
- *allergic reactions*
- *lack of efficacy*
- *drug abuse or dependency*
- *hospitalization*
- *death*
- *any suspected transmission of an infectious agent via a pharmaceutical or over the counter product (e.g. patient develops an eye infection after using a pharmaceutical or over the counter eye product)*

Unexpected Therapeutic Effect

Any description of a beneficial therapeutic effect of a product aside from the use for which it had been given (e.g., patient takes a product for high cholesterol and notices decreased insomnia) must also be forwarded as a product safety report.

Circumstances that May Lead to Adverse Events

Circumstances that may increase a patient's/consumer's risk of developing an adverse event **regardless of whether there was an adverse event need to be reported.** These include:

- **drug misuse, drug overdose or drug withdrawal**
- **exposure during pregnancy**—*a pregnancy where the fetus (from pre-embryo to birth) may have been exposed to medicinal product through either maternal or paternal exposure.*
- **exposure during breastfeeding**—*a situation where an infant or child may have been exposed through breast milk to any pharmaceutical or over the counter medicinal product during breastfeeding by a female taking the product.*
- **extravasation**—*this occurs when a drug given intravenously leaks from a vein into the surrounding tissue.*
- **medication error**—*any unintentional errors in the prescribing, dispensing, or administration of the product, that may lead to inappropriate medication use or patient harm, while in the control of the HCP, patient or consumer.*
- **occupational exposure**—*this occurs when a person (e.g., HCP, home-care worker, hospital cleaner, porter) comes into unplanned direct contact with a product when performing job duties (e.g., splashing injectable solution on the skin).*
- **off-label use**—*this refers to any use of an authorized medicinal product prescribed for purposes outside the conditions of the product label/instructions.*

Medical Device Complaints and Product Complaints

Medical device complaints and product complaints must also be forwarded as product safety reports whether or not there are any associated adverse events.

- *A **medical device complaint** is any written, electronic, or oral communication of dissatisfaction relative to the appearance, identity, quality, durability, reliability, safety, effectiveness, instructions for use, or performance of a medical device or product with a medical device component.*
- *A **product complaint** is any written, electronic or oral expression of dissatisfaction relative to the physical properties, condition, package insert, and/or packaging of a product (e.g., cracked bottle, discoloration or crumbling of tablets, terrible odor, torn label, empty sealed bottle, vial is leaking liquid, incorrect product in box, suspected or confirmed counterfeit products).*