

Off-Label Drug Use Rife in Hospitalized Children

BY MARY ANN MOON
Contributing Writer

Nearly 80% of hospitalized children were treated with drugs not approved for use at their age for any indication in a large U.S. study, reported Dr. Samir S. Shah of Children's Hospital of Philadelphia and associates.

The researchers conducted what they described as the first study of off-label drug use in hospitalized American children because so little is known about the topic. This scarcity of data "can lead to the withholding of potentially beneficial treatments or to administration of potentially harmful treatments," they said in the Archives of Pediatric and Adolescent Medicine.

'Off-label drug use' referred solely to whether the patient was younger than the FDA-approved age for using an agent, not to the FDA indications for a drug's use.

of Pediatric and Adolescent Medicine.

"Though off-label drug use also occurs in adults, the problem is substantially greater in children because many drugs have not been tested in any pediatric population for any indication," they noted. "We still have incomplete knowledge about the safety and efficacy of many medications commonly used to treat children across a range of drug classes and clinical diagnoses."

Dr. Shah and associates used an administrative database from the Pediatric Health Information System to review drug use in 355,409 children hospitalized in 2004 at 31 tertiary-care pediatric medical centers throughout the country. The patient population was racially and ethnically diverse as well as geographically heterogeneous.

For the purposes of this study, "off-label drug use" referred solely to whether the patient was younger than the Food and Drug Administration-approved age for using the agent, not to FDA-approved indications for use, said Dr. Shah, who is also of the University of Pennsylvania's Center for Clinical Epidemiology and Biostatistics, and associates.

The investigators focused on 90 drugs that were either used frequently or included on an FDA list of medications that are recommended for further study in pe-

diatric patients. At least one of these drugs was used off-label in more than 297,000 patients (79%) during the 1-year study. Off-label use accounted for more than \$270 million in expenditures on medications, which was 40% of total drug costs, the investigators said (Arch. Ped. Adolesc. Med. 2007;161:282-90).

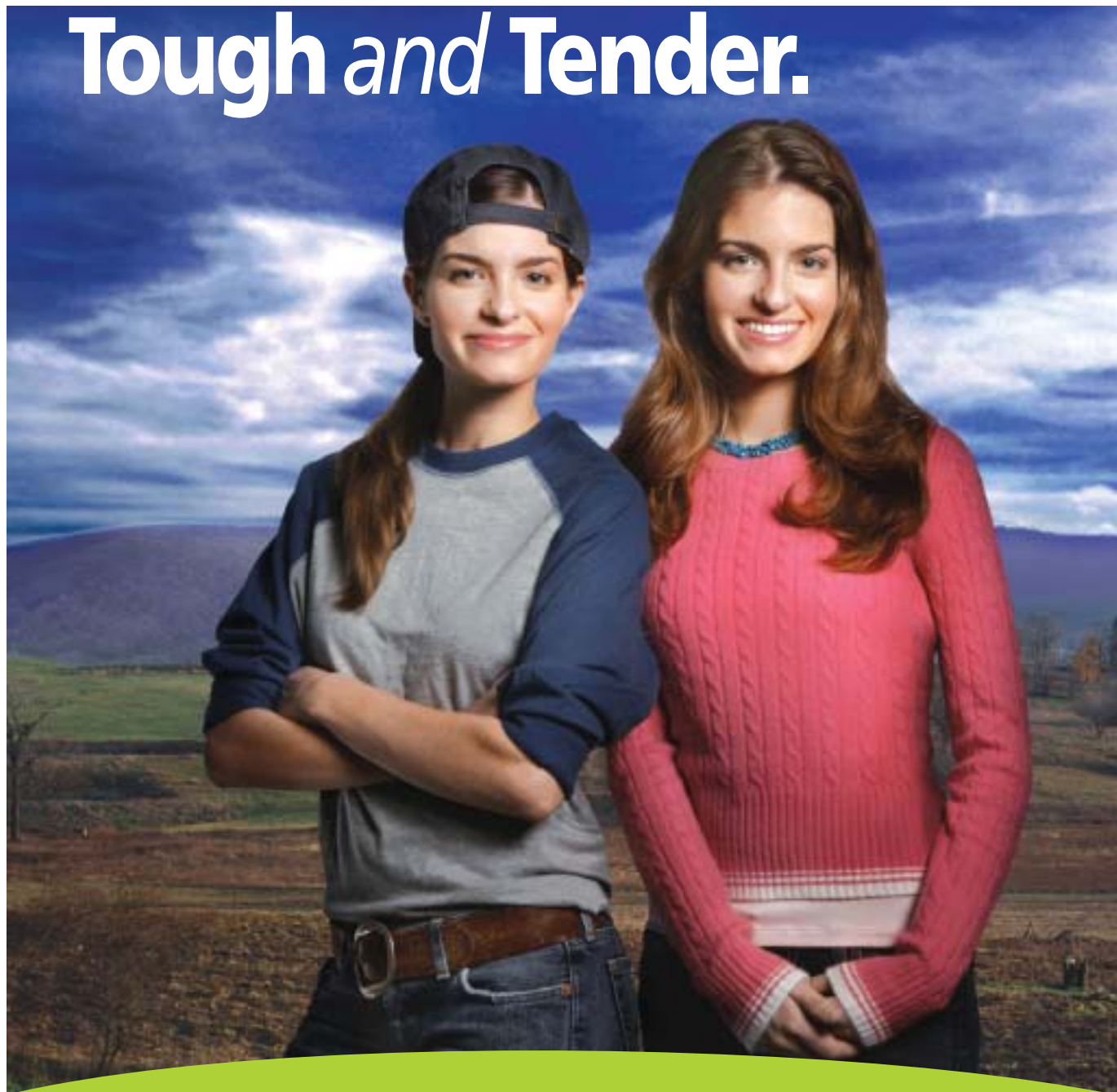
When the data were broken down by 24 diagnostic categories such as infectious diseases, traumatic injury, circulatory disorders, GI problems, or respiratory dis-

eases, every category had at least one drug that was used off-label in more than half of patients. Among children undergoing procedures or surgeries, at least one drug was used off-label in over 90%.

Off-label drug use was more common in more severely ill children, in those undergoing surgery, and in those older than 28 days of age, but variables such as patient race, gender, payer, or geographic region showed no correlations with off-label drug use. Concerning the correlation with sever-

ity of illness, "We suspect that in many cases drugs are prescribed off-label in children who are already critically ill because either they have failed approved therapy or there are few situation-specific FDA-approved options," Dr. Shah and associates said.

They added that these findings have shed light on the magnitude of the problem of off-label drug use in children, and should "assist in further prioritizing certain drugs for additional pediatric studies of safety and efficacy." ■



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