

# Readers' Forum

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## *To the Editor:*

I was delighted to see the research article in your July/August issue on "Awareness of the Bicycle Helmet Law in North Carolina." Hopefully, it will serve as a reminder to the primary care providers in your readership that a little guidance to children and parents alike on the efficacy of helmets can save lives and reduce serious injuries.

Interestingly, the authors seem more pessimistic about compliance with the law than those of us on the NC Child Fatality Task Force who pushed for passage of the law in 2000-2001. The authors seem disappointed that regular helmet use in Pitt County increased in the 5 years after passage from less than 10% just before passage to 40%. Though much more improvement is needed, those of us involved with children's safety issues are encouraged by this significant increase in helmet use, especially since the law does not require those age 16 and older to wear helmets. Thus, parents often are not the role models they need to be.



While acknowledging the limitations of a one-county study, the authors neglect to present statewide data on the measure of greatest importance to the Task Force: bicycle-related deaths in children. In the 6 years prior to consideration and passage of the law (1994-1999) there were 71 bicycle-related deaths among children in North Carolina. In the 6 years since then (2000-2005), there were 43. That's a remarkable 40% reduction in such deaths. Given that the number of children has been increasing each year, it is likely that the death rate has dropped by almost half!

While these data are particularly encouraging, the research article makes it clear that we have a long way to go. Raising awareness is critical. Let's hope the article does just that.

*Tom Vitaglione, Chair  
NC Child Fatality Task Force  
1300 St. Mary's Street, Suite 500  
Raleigh, NC 27605  
919-834-6623 Ext. 235  
tom@ncchild.net*

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## *To the Editor:*

Concern has been raised recently by both consumers and physicians about the safety of drugs and implants after release to the market and the widespread television advertising of these new medications and devices. These two issues are important and closely interrelated. Last year, the Institute of Medicine of the National Academies issued a report calling for the Food and Drug Administration (FDA) to increase vigilance for possible drug complications after release. This report also recommended that direct marketing of a new medication to consumers should be restricted for two years after release of the new drug.

There has been an explosion of new and expensive technology in total hip and knee replacement devices. With the increasing prevalence of arthritis in the maturing baby-boomer generation, the orthopaedic device companies have also increased direct marketing of joint replacement products to consumers. Some examples include ceramic hip bearings, metal on metal hip resurfacing, rotating plastic knee replacements, knee devices designed for women only, and

computer assisted surgery. Obviously, the orthopaedic device companies must be getting a good return for their advertising budgets. However, do consumer-patients truly benefit from this new expensive technology?

At a recent national meeting of orthopaedic surgeons in San Diego, data were presented on all these new devices. There is yet no proven benefit from these new, more expensive devices compared to standard hip and knee implants. Computer-assisted orthopaedic surgery has yet to improve patients' outcomes. The American Academy of Orthopaedic Surgeons, the Hip Society, and the Knee Society have again called on the Centers for Medicare and Medicaid Services to establish a national registry for hip and knee replacements. Such a registry would identify, at an earlier time, problematic or less effective devices. The United States has a much higher rate of revision (redo) hip and knee replacement surgery than other countries such as Canada, Sweden, and Norway, which have such national registries. With patients changing insurance plans and physicians frequently, only a national registry will detect the problematic devices early. At present, patients and

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## Readers' Forum continued

Body or a diffuse arthritis, fever, allergic reaction, chills, malaise, chest pain, substernal, neck rigidity, photosensitivity reaction. Rare: abdomen enlarged, face edema, hangerweight effect. **Cardiovascular System:** hyperloston, myocardial infarct, electrocardiogram abnormal, migraine, syncope, angina pectoris, bundle branch block, palpitation, sinus bradycardia, tachycardia. Rare: bradycardia, pulmonary embolus, supraventricular tachycardia, thrombophlebitis, myocardial infarction, QTc prolongation and ventricular tachycardia. **Digestive System:** diarrhea, nausea, abdominal pain, vomiting, dyspepsia, flatulence, constipation, dry mouth, eructation, gastroenteritis, rectal hemorrhage, reflux, acidosis, cholelithiasis, mouth ulceration, stomatitis, dysphagia, gingivitis, cheilitis, increased appetite, abnormal stools, colitis, esophagitis, glossitis, parotiditis, proctitis. Rare: bloody diarrhea, cholangitis, duodenitis, gastrointestinal hemorrhage, hepatic encephalopathy, hepatitis, hepatitis, liver fatty deposit, solitary gland enlargement, tumor. **Endocrine System:** hyperthyroidism, hypothyroidism. **Renal & Urologic System:** anemia, tachycardia, lymphadenopathy, hypochromic anemia. **Metabolic & Nutritional Disorders:** peripheral edema, edema, weight gain, gout, dehydration, weight loss. **Musculo-Skeletal System:** myalgia, arthritis, leg cramps, bone pain, arthralgia, burrula. Rare: bruxism. **Nervous System:** insomnia, anxiety, dizziness, depression, nervousness, somnolence, hyperkinesia, neuritis, vertigo, confusion, abnormal dreams, libido decreased, neuropathy, paresthesia, tremor. Rare: agitation, amnesia, confusion, estropomidal syndrome, hyperkinesia. **Respiratory System:** dyspnea, asthma, epistaxis, laryngitis, hiccup, hyperventilation. Rare: apnea, hypoxemia. **Skin and Appendages:** rash, pruritus, sweating, urticaria, alopecia. Rare: dry skin, herpes zoster, psoriasis, skin discoloration. **Special Senses:** cataract, amblyopia, glaucoma, dry eyes, abnormal vision, double, otitis media. Rare: corneal opacity, blurry vision, diplopia, redness, eye pain, retinal degeneration, strabismus. **Urogenital System:** cystitis, urinary frequency, dyspareunia, dysuria, kidney calculus, retrograde, polyuria. Rare: breast enlargement, hematuria, impotence, leukorrhea, menorrhagia, orchitis, urinary incontinence.

**Laboratory Values:** The following changes in laboratory parameters were reported as adverse events: abnormal prothrombin, albuminuria, creatine phosphokinase increased, erythrocytes abnormal, hypercholesterolemia, hyperglycemia, hyperkalemia, hypocalcemia, hypomagnesemia, leukocytosis, leukorrhea, liver function tests abnormal, prothrombin specific antigen increase, SGPT increased, urine abnormality, WBC abnormal.

In controlled clinical studies, 37456 (12.2%) patients treated with rofecoxib and 27277 (12.8%) patients treated with placebo developed treatment emergent abnormalities (which were either new or study or present at study entry with an increase of 1.25 x baseline value in SGOT (AST), SGPT (ALT), or both). None of the three rofecoxib patients experienced chills, fever, right upper quadrant pain, nausea or jaundice.

**Combination Treatment with Amoxicillin and Clarithromycin:** In clinical trials using combination therapy with rofecoxib plus amoxicillin and clarithromycin (RAC), no adverse events unique to this drug combination were observed. In the U.S. multicenter study, the most frequently reported drug related adverse events for patients who received RAC therapy for 7 or 10 days were diarrhea (6% and 7%) and taste perversion (6% and 12%), respectively.

No clinically significant laboratory abnormalities particular to the drug combination were observed.

For more information on adverse events or laboratory changes with amoxicillin or clarithromycin, refer to their respective package prescribing information, **ADVERSE REACTIONS** section.

**Post-Marketing Adverse Events:** Additional adverse events reported from worldwide marketing experience with rofecoxib sodium are: sudden death; coma and hypermagnesemia; jaundice; rhabdomyolysis; disorientation and delirium; anaphylactic angioedema; bulous and other drug eruptions of the skin; severe dermatologic reactions, including toxic epidermal necrolysis (some fatal), Stevens-Johnson syndrome, and erythema multiforme; interstitial pneumonia; interstitial nephritis; and TSH elevations. In most instances, the relationship to rofecoxib sodium was unclear. In addition, agranulocytosis, hemolytic anemia, leukopenia, pancytopenia, and thrombocytopenia have been reported. Increases in prothrombin time/INR in patients treated with concomitant warfarin have been reported.

### OVERDOSAGE

Because strategies for the management of overdose are continually evolving, it is advisable to contact a Poison Control Center to determine the latest recommendations for the management of an overdose of any drug. There has been no experience with large overdoses with rofecoxib. Seven reports of accidental overdose with rofecoxib have been received. The maximum reported overdose was 60 mg. There were no clinical signs or symptoms associated with any reported overdose. Patients with Zolinger-Ellison syndrome have been treated with up to 120 mg rofecoxib QD, for specific antidote for rofecoxib is known. Rofecoxib is extensively protein bound and is not readily dialyzable. In the event of overdose, treatment should be symptomatic and supportive.

Single oral doses of rofecoxib of 785 mg/kg and 1024 mg/kg were lethal to mice and rats, respectively. The single oral dose of 2000 mg/kg was not lethal to dogs. The major symptoms of acute toxicity were hypothermia, labored respiration, lateral or prone position and convulsion in mice and rats and volery diarrhea, tremor, convulsion and coma in dogs.

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physicians can rely only on institutional (Mayo Clinic) or personal surgeon (UNC) databases for this information. Individual problems with devices such as squeaking ceramic hip replacements are likely underreported to the FDA at present. Patients should also realize that the experience and skill of the surgeon is more important for the long-term success of a hip or knee replacement than the use of the newest or most advertised product.

Patients should write their national legislators this year to encourage the FDA and the Centers for Medicare and Medicaid Services to enact a national registry for hip and knee replacements. Television and print advertising of these devices to patients should be discouraged. Until this system is functional, patients with hip and knee replacements should have regular checkups of their artificial joints by their surgeon.

*Paul F. Lachiewicz, MD*

*Professor of Orthopaedics*

*The University of North Carolina at Chapel Hill*

Coming in the January/February  
2008 issue of the

**North Carolina  
Medical Journal**

a look at:

**Health Concerns  
for Returning  
Military  
Personnel**