Adding life to the elder years

John F. Kennedy once said, "We have added years to life, now we must add life to those years."[1] These words have guided the mission of geriatric clinical, educational, and academic programs nationwide. The "geriatric imperative" of the 1970s, a concept promoted through the National Institute on Aging under the direction of Robert Butler, MD, presented compelling reasons for our nation's health professions schools to respond to unmet healthcare needs of the elderly.[2] This imperative cited a demographic, economic, academic, and attitudinal basis.

The demographic and economic aspects of the geriatric imperative are evidenced by the "graying of America," that is, the rapid rise of the geriatric population, who are the highest users of our healthcare resources at a time when the United States is recognizing that its healthcare resources are not endless. The old old, persons older than 85 years, are the most rapidly growing segment of the US population. They have the highest degree of functional limitations and the greatest use of long-term care.[3] By the year 2050, there will be an estimated 1 million centagenarians in the United States.[4]

The academic basis for the geriatric imperative is seen in the need for important clinical information of geriatric medicine to be appropriately included in the curriculum of medical schools, graduate medical education programs, continuing medical education courses, and the successful establishment of training programs to train geriatricians to teach geriatric medicine.[5] Likewise, the academic justification of the geriatric imperative is apparent in the need for long-neglected research in healthcare of the elderly, particularly chronic illness that is now causing functional decline.

Finally, the attitudinal dimension of the geriatric imperative calls for the need to dispel myths about medical interventions among the elderly. These myths frequently lead to ageism, a prejudice against the elderly and an attitude thought to be prevalent in healthcare. Such prejudice places the elderly at risk for rationing healthcare resources nationwide. Stemming from this geriatric imperative of the late 1970s, many pivotal developments have emerged that respond to the unmet healthcare needs of the elderly. These developments include the establishment of academic geriatric medicine programs in medical schools, the creation of geriatric fellowship programs, the development of the certificate of added qualifications in geriatrics, advancements in gerontologic research, and the creation of geriatric assessment programs.[6] The osteopathic medical profession has made significant contributions in these areas. Great advances have been documented in the incorporation of geriatrics in the curriculum of the colleges of osteopathic medicine (COMs). Also, two of the nine federally funded geriatrics fellowship programs emanate from COMs.

Despite these significant strides, the research and education goals in geriatrics are far from being achieved. Beginning on page **712**, "Functional abilities of elderly survivors of intensive care," by Dr Broslawski and colleagues, addresses two important issues in geriatric care. Specifically, this prospective, randomized study identifies functional outcomes of elderly patients treated in an intensive care setting. Along with other conclusions, the study indicates that poor functional outcomes are directly related to the length of stay in the intensive care unit, as well as total hospital days. Poor functional outcomes were *not* found to be related to the patients' age or severity of illness.

These data offer the potential to identify strategies that would lead to improved function after hospitalization, as well as the decreased need for long-term care institutions and home care services, and with that, the potential for cost savings. By demonstrating that older persons have as good a functional outcome to critical care interventions as do younger persons, this study supports the potential benefits of critical care intervention—even among the aged. These data

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Esgic*plus*™ tablets

Butalbital 50mg **(Warning: May be habit forming)**
/Acetaminophen 500mg/Caffeine 40mg

References: 1. Benson GD. Hepatotoxicity following the therapeutic use of antipyretic analgesics. *Am J Med.* 1983;75(suppl 5A):85-93. **2.** Jick H. Effects of aspirin and acetaminophen in gastro-intestinal hemorrhage. *Arch Intern Med.* 1981;141:316-321. **3.** Mielke CH Jr. Comparative effects of aspirin and acetaminophen on hemostasis. *Arch Intern Med.* 1981;141:305-310. **4.** Hansten PD. *Drug Interactions.* 5th ed. Philadelphia, PA: Lea & Febiger; 1985, p. 95. **5.** Insel PA. Analgesic-antipyretics and antiinflammatory agents; drugs employed in the treatment of rheumatoid arthritis and gout. In: Gilman AG, Rall TW, Nies AS, Taylor P, eds. *The Pharmacological Basis of Therapeutics.* 8th ed. New York, NY: Pergamon Press; 1990:638-681.

ESGIC-PLUS™ Tablets
(Butalbital, Acetaminophen and Caffeine Tablets, USP)
50mg/500mg/40mg

Brief Prescribing Information: (Please see package insert for full prescribing information) Each Esgic-plus™ Tablet contains: Butalbital, USP 50 mg. WARNING: May be habit forming. Acetaminophen, USP 500 mg, Caffeine, USP 40 mg. In addition each tablet contains the following inactive ingredients: microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide and stearic acid.

CONTRAINDICATIONS: This product is contraindicated under the following conditions: • Hypersensitivity or intolerance to any component of this product. • Patients with porphyria. **WARNINGS:** Butalbital is habit-forming and potentially abusable. Consequently, the extended use of this product is not recommended.

PRECAUTIONS: General: Esgic-plus™ Tablets should be prescribed with caution in certain special-risk patients, such as the elderly or debilitated, and those with severe impairment of renal or hepatic function, or acute abdominal conditions. **Information for Patients:** This product may impair mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. Such tasks should be avoided while taking this product. Alcohol and other CNS depressants may produce an additive CNS depression, when taken with this combination product, and should be avoided. Butalbital may be habit-forming. Patients should take the drug only for as long as it is prescribed, in the amounts prescribed, and no more frequently than prescribed. **Laboratory Tests:** In patients with severe hepatic or renal disease, effects of therapy should be monitored with serial liver and/or renal function tests. **Drug Interactions:** The CNS effects of butalbital may be enhanced by monoamine oxidase (MAO) inhibitors. Esgic-plus™ Tablets may enhance the effects of: other narcotic analgesics, alcohol, general anesthetics, tranquilizers such as chlordiazepoxide, sedative-hypnotics, or other CNS depressants, causing increased CNS depression. **Drug/Laboratory Test Interactions:** Acetaminophen may produce false-positive test results for urinary 5-hydroxyindoleacetic acid. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** No adequate studies have been conducted in animals to determine whether acetaminophen or butalbital have a potential for carcinogenesis, mutagenesis, or impairment of fertility. **Pregnancy:** *Teratogenic Effects:* Pregnancy Category C: Animal reproduction studies have not been conducted with this combination product. It is also not known whether Esgic-plus™ Tablets can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be given to a pregnant woman only when clearly needed. *Nonteratogenic Effects:* Withdrawal seizures were reported in a two-day-old male infant whose mother had taken a butalbital-containing drug during the last two months of pregnancy. Butalbital was found in the infant's serum. The infant was given phenobarbital 5 mg/kg, which was tapered without further seizure or other withdrawal symptoms. **Nursing Mothers:** Caffeine, barbiturates and acetaminophen are excreted in breast milk in small amounts, but the significance of their effects on nursing infants is not known. Because of potential for serious adverse reactions in nursing infants from Esgic-plus™ Tablets, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** Safety and effectiveness in children below the age of 12 have not been established.

ADVERSE REACTIONS: Frequently Observed: The most frequently reported adverse reactions are drowsiness, light-headedness, dizziness, sedation, shortness of breath, nausea, vomiting, abdominal pain, and intoxicated feeling. **Infrequently Observed:** All adverse events tabulated below are classified as infrequent. *Central Nervous:* headache, shaky feeling, tingling, agitation, fainting, fatigue, heavy eyelids, high energy, hot spells, numbness, sluggishness, seizure. Mental confusion, excitement or depression can also occur due to intolerance, particularly in elderly or debilitated patients, or due to overdosage of butalbital. *Autonomic Nervous:* dry mouth, hyperhidrosis. *Gastrointestinal:* difficulty swallowing, heartburn, flatulence, constipation. *Cardiovascular:* tachycardia. *Musculoskeletal:* leg pain, muscle fatigue. *Genitourinary:* diuresis. *Miscellaneous:* pruritus, fever, earache, nasal congestion, tinnitus, euphoria, allergic reactions. Several cases of dermatological reactions, including toxic epidermal necrolysis and erythema multiforme, have been reported. The following adverse drug events may be borne in mind as potential effects of the components of this product. Potential effects of high dosage are listed in the OVERDOSAGE section. *Acetaminophen:* allergic reactions, rash, thrombocytopenia, agranulocytosis. *Caffeine:* cardiac stimulation, irritability, tremor, dependence, nephrotoxicity, hyperglycemia.

DRUG ABUSE AND DEPENDENCE: Abuse and Dependence: Butalbital: *Barbiturates may be habit-forming:* Tolerance, psychological dependence, and physical dependence may occur especially following prolonged use of high doses of barbiturates. The average daily dose for the barbiturate addict is usually about 1500 mg. As tolerance to barbiturates develops, the amount needed to maintain the same level of intoxication increases; tolerance to a fatal dosage, however, does not increase more than two-fold. As this occurs, the margin between an intoxication dosage and fatal dosage becomes smaller. The lethal dose of a barbiturate is far less if alcohol is also ingested. Major withdrawal symptoms (convulsions and delirium) may occur within 16 hours and last up to 5 days after abrupt cessation of these drugs. Intensity of withdrawal symptoms gradually declines over a period of approximately 15 days. Treatment of barbiturate dependence consists of cautious and gradual withdrawal of the drug. Barbiturate-dependent patients can be withdrawn by using a number of different withdrawal regimens. One method involves initiating treatment at the patient's regular dosage level and gradually decreasing the daily dosage as tolerated by the patient.

OVERDOSAGE: Following an acute overdosage of Esgic-plus™ Tablets, toxicity may result from the barbiturate or the acetaminophen. Toxicity due to caffeine is less likely, due to the relatively small amounts in this formulation. **Signs and Symptoms:** Toxicity from barbiturate poisoning includes drowsiness, confusion, and coma; respiratory depression; hypotension; and hypovolemic shock. In acetaminophen overdosage: dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necroses, hypoglycemic coma and thrombocytopenia may also occur. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams, or fatalities with less than 15 grams. Acute caffeine poisoning may cause insomnia, restlessness, tremor, and delirium, tachycardia and extrasystoles. **Treatment:** A single or multiple overdose with this combination product is a potentially lethal polydrug overdose, and consultation with a regional poison control center is recommended. Immediate treatment includes support of cardiorespiratory function and measures to reduce drug absorption. Vomiting should be induced mechanically, or with syrup of ipecac, if the patient is alert (adequate pharyngeal and laryngeal reflexes). Oral activated charcoal (1 g/kg) should follow gastric emptying. The first dose should be accompanied by an appropriate cathartic. If repeated doses are used, the cathartic might be included with alternate doses as required. Hypotension is usually hypovolemic and should respond to fluids. Pressors should be avoided. A cuffed endotracheal tube should be inserted before gastric lavage of the unconscious patient and, when necessary, to provide assisted respiration. If renal function is normal, forced diuresis may aid in the elimination of the barbiturate. Alkalinization of the urine increases renal excretion of some barbiturates, especially phenobarbital. Meticulous attention should be given to maintaining adequate pulmonary ventilation. In severe cases of intoxication, peritoneal dialysis, or preferably hemodialysis may be considered. If hypoprothrombinemia occurs due to acetaminophen overdose, vitamin K should be administered intravenously. If the dose of acetaminophen may have exceeded 140 mg/kg, acetylcysteine should be administered as early as possible. Serum acetaminophen levels should be obtained, since levels four or more hours following ingestion help predict acetaminophen toxicity. Do not await acetaminophen assay results before initiating treatment. Hepatic enzymes should be obtained initially, and repeated at 24-hour intervals. Methemoglobinemia over 30% should be treated with methylene blue by slow intravenous administration.

Toxic Doses (for adults): Butalbital: toxic dose 1g (20 tablets); Acetaminophen: toxic dose 10g (20 tablets); Caffeine: toxic dose 1g (25 tablets). CAUTION: Federal law prohibits dispensing without prescription.

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are important in a socioeconomic environment where age is being used as a potential mechanism to limit increasingly scarce healthcare resources on the basis of ineffectiveness without data to support such conclusions.

A tremendous need exists for more gerontologic research to document beneficial outcomes of interventions that improve function, as well as to provide data to disprove several misconceptions regarding healthcare issues for the elderly. In this way, the goal of "adding life to years" *can* be achieved.♦

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