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DIRECTOR

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...334-844-4400

Auburn University Harrison School of Pharmacy Drug Information Newsletter

# Auburn HealthLink

Volume 3 Issue 1 May 2003

## LET US INTRODUCE OURSELVES

**T**he Auburn University Harrison School of Pharmacy, under a few different names, has been serving the Alabama community since 1886. Drug information services, through the school of pharmacy have been available for many years, and the tradition continues. Our mission is to provide unbiased drug information as a support to Alabama health care professionals for use in patient care, education and research. In addition we exist to provide pharmacy students and residents with the opportunity and training to learn and develop drug information skills and to collaborate and contribute to the areas of drug information practice, drug policy and medication criteria development and drug education research.

The Auburn University, Harrison School of Pharmacy Drug Information and Learning Resource Center (AU DIC) is housed in the Walker Building in the middle of the Auburn University campus, conveniently located just a block from Jordan-Hare Stadium.

The AU DIC has an impressive array of pharmacy, pharmacotherapeutic and medical references. This includes an up-to-date library of textbooks and references in formats ranging from print books (bound and loose leaf), electronic references (some updated daily), and even a microfiche archive file of journal articles. In addition, the Center subscribes to the major pharmacy and medical journals, some of which are available in both print and electronic forms. We are also a part of the AU library system that gives us access to a very large collection of medical publications, a multitude of online search systems (eg, Medline), a large library of online journals, and

via a library consortium, access to a great number of other journals and references.

In addition to the tremendous amount of information available, there are qualified staff that know how to use it. There are two full time faculty/staff. Bernie Olin, Pharm.D. is the director of the AU DIC and has been in the drug information field for over 20 years.

Margaret Thrower, Pharm.D. is a drug information specialist who completed a postgraduate drug information specialty residency prior to joining the faculty of Auburn. The Center is also a training site for senior pharmacy students and Pharmacy Practice residents doing their post-graduate work at Auburn.

Please enjoy our newsletter. It will be issued on a regular basis and will contain current and useful drug information that we hope will be of value to your practice.

If you have a drug-related question that exceeds the boundaries of your reference shelf, please give us a call. We will do our best to deliver accurate, unbiased and timely information. *See the back page for all contact information.*



Bernie Olin, Pharm.D.,  
Director, AU DIC



Margaret Thrower  
Pharm.D., Drug  
Information Specialist

# Web Health Links...

## Antibacterial Labeling to Include Drug- Resistance Statements

Firms that manufacture oral or intravenous drugs have one year to add to those products' labeling nine sentences aimed at reducing the emergence of drug-resistance bacteria, according to a new rule from the Food and Drug Administration. The rule applies to antibacterial drugs indicated primarily for the prevention or treatment of bacterial infections other than mycobacterial ones.

<http://www.fda.gov/OHRMS/DOCKETS/98fr/00n-1463-nfr00001.pdf>

## Patient Safety Surpasses HIPAA as Top Technology Concern

More health care information technology (IT) executives view patient safety, not the Health Insurance Portability and Accountability Act of 1996, as their facility's top IT concern, according to a survey released by the Health Information Management Systems Society. Sixty-four percent of the nearly 300 respondents selected computerized prescriber order entry as the health care application most important to their facility for the next two years.

<http://www.himss.org/ASP/ContentRedirector.asp?ContentId=27263>

## Ephedra's Effects Prompt the Most Calls

Poison control centers in 2001 fielded far more inquiries about adverse reactions to ephedra-containing products than to any other herbal product, according to a study funded by the National Center for Complementary and Alternative Medicine.

Bent S, Tiedt TN, Odden MC, Shlipak MG, The Relative Safety of Ephedra Compared with Other Herbal Products. *Ann Intern Med.* 2003;138:000-000. Note: This may be even more prominent with the death of Baltimore Oriole's pitcher Steve Bechler, 2/17/03 that may be linked to an ephedrine-containing supplement. Also, partially in response to the events involving Mr. Bechler, the FDA announced a series of actions to address the concerns about ephedra in a February 28, 2003 statement.

<http://www.fda.gov/bbs/topics/NEWS/2003/NEW00875.html>

## Training new Doc's in Old Therapies

Wetzel MS, Kaptchuk TJ, Haramati A, Eisenberg DM. Complementary and alternative medical therapies: Implications for medical education. *Ann Intern Med* 2003 Feb 4;138:191-96.

It seems that medical education is trying to address the issue of training for new physicians. Will pharmacy lead or follow?

## Check Those Serzone Tablets

In a "Dear Health Care Provider" letter dated 12/9/02 and recently distributed by MedWatch, Bristol-Myers Squibb Company asked clinicians to encourage their nefazodone patients to check the contents of their prescription bottle against a Serzone patient information leaflet. The company said that pharmacies are giving patients the leaflet when they have their Serzone prescription filled. There have apparently been numerous reports of dispensing errors due to confusing Serzone and Seroquel tablets due to similar spellings, dose strengths and dosage.

[http://www.fda.gov/medwatch/SAFETY/2003/Serzone-squibb\\_deardoc.pdf](http://www.fda.gov/medwatch/SAFETY/2003/Serzone-squibb_deardoc.pdf)

## One a Day, Still the Way

Although the patient population and parameters of study were very restrictive, a study has confirmed rather old advice that a daily multivitamin and mineral supplement contributed to better health.

Barringer TA, Kirk JK, Santaniello AC, Foley KL, Michielutte R. Effect of a multivitamin and mineral supplement on infection and quality of life. *Ann Intern Med* 2003 Mar 4;138:365-71

## Risperidone Linked to Stroke in Certain Elderly Patients

Janssen Pharmaceutica Inc. issued a "Dear Healthcare Provider" letter on April 16, 2003 warning that cerebrovascular adverse events, including stroke, occurred at a significantly higher rate in elderly patients with dementia-related psychosis who received risperidone than in those who did not. This information has been added to the most recent package labeling. Risperidone, or Risperdal®, is indicated for the treatment of schizophrenia but not dementia.

[http://www.janssen.com/ourcompanynews\\_detail.jsp?id=041603\\_1](http://www.janssen.com/ourcompanynews_detail.jsp?id=041603_1)

## FDA Approves New Treatment for Eye Inflammation

Vigamox™, a preservative-free ophthalmic solution containing 0.5% moxifloxacin, was approved April 15, 2003 by the Food and Drug Administration. Alcon Inc. will market the product for the treatment of conjunctivitis caused by susceptible strains of bacteria, including *Chlamydia trachomatis*.

<http://www.accessdata.fda.gov/scripts/cder/drugcat/index.cfm?fuseaction=Search.Label>

## Search for a Cure: Alzheimer's

*Eileen R. Zeanah, Pharm. D. Candidate,  
Harrison School of Pharmacy*

Imagine a world filled with 4 million people suffering from a devastating disease, Alzheimer's Disease (AD); now realize that this is a reality. One of those lives includes a retired chemistry professor, BR who is 80 years old, who never dreamed of the impact AD would one day have on his life. Now after eight years, he completely depends on the care of his wife and staff of an assisted living facility to function in a world of unknowns. Initially he noticed difficulty remembering names, appointments and directions. Simple activities of daily living such as bathing, dressing, tying his shoes and eating are too complex for a man who once taught graduate level chemistry. He has a family history of AD (mother, father, and one brother). Presently he is taking rivastigmine (Exelon®), a member of the only class of medication, anticholinesterase inhibitors, that have been shown to decrease the progression or stabilize AD. Unfortunately BR, along with the other 4 million Americans, has lived during a time when AD is being extensively researched in order to find a cure, more effective treatment, or a preventative agent. Hopefully, one day a therapy will prove effective in the prevention of AD for those with a strong family history of AD like BR or a genetic predisposition for AD. Let's take a look at the latest development of agents for the prevention of AD.

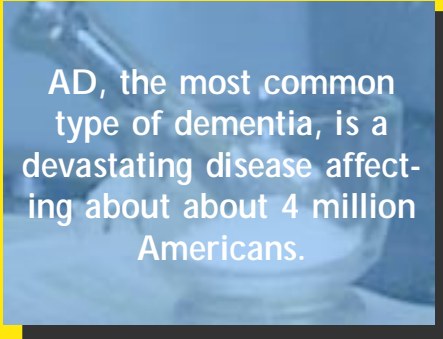
### THE FACTS

AD, the most common type of dementia, is a devastating disease affecting about 4 million Americans. Unless

a cure is found by the year 2050, it is estimated that nearly 14 million Americans will have AD, comparable to the 17 million who presently have diabetes. The average lifespan after the diagnosis of AD is 8 years but is highly variable and may be as long as 20 years. Many of these years are spent in a nursing home with yearly costs of about \$47,000. The U.S. spends at least \$100 billion annually on AD and in 2002 the federal government estimates spending \$599 million for AD research.<sup>1,2</sup>

### PATHOPHYSIOLOGY

Nerve cells of the brain cease to function, lose connection with other neurons, and die. Amyloid plaques and neurofibrillary tangles (NFT) in the brain are hallmark characteristics associated with AD. In addition, genetic factors may play a role. An APO E4 allele on chromosome 19 is thought to contribute to  $\beta$ -amyloid plaque formation. Plaques, the initiating step in AD, are entangled axons and dendrites along with insoluble deposits of  $\beta$ -amyloid which are cleaved from amyloid precursor protein (APP). Inflammation associated with plaques is related to the microglia and astrocytes that release neurotoxic factors (i.e., TNF- $\alpha$ , IL-6).<sup>3,4</sup> One theory suggests that nerve cells are destroyed due to plaque build up in the brain from increased levels of cholesterol which reduce the blood supply in the brain.<sup>5</sup> In AD, tau protein is chemically changed causing it to twist into helical filaments that tangle to form the second hallmark characteristic of AD, NFTs. Normally tau protein aids in the development of functional microtubules to support cell life but in AD, they become nonfunctional. This leads to areas of neurodegeneration resulting in fewer neurons releasing the neurotransmitter, acetylcholine (Ach).<sup>3,4</sup> This re-



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...continued—pg. 5

### Web Health Links—continued

#### New Antiinfective Approved for Respiratory Tract Infections

The Food and Drug Administration recently approved the marketing of gemifloxacin mesylate, or Factive™, on April 4, 2003. It is for the treatment of acute exacerbation of chronic bronchitis and mild to moderate community-acquired pneumonia caused by bacterial strains susceptible to the fluoroquinolone.

GeneSoft Pharmaceuticals Inc., which will sell the product in the United States, does not indicate when Factive™ will be available in pharmacies. <http://www.genesoft.com/news.html>

#### Need Information on HIPAA Privacy?

The Health and Human Services office charged with upholding the medical privacy regulations in the Health Insurance Port-

...continued—pg. 6

## Significant New Therapeutic Drugs for 2002

Generic Name	Trade Name	Mfg.	Dose Form	Description	Indications
Adalimumab	Humira	Abbott <a href="http://www.humira.com">www.humira.com</a>	Injection	IgG1 monoclonal antibody	Rheumatoid arthritis
Adefovir dipivoxil	Hepsera	Gilead <a href="http://www.gilead.com">www.gilead.com</a>	Tablets, oral	Acyclic nucleotide analog	Chronic hepatitis B
Aripiprazole	Abilify	Otsuka <a href="http://www.abilify.com">www.abilify.com</a>	Tablets, oral	Antipsychotic	Schizophrenia
Atomoxetine HCl	Strattera	Eli Lilly <a href="http://www.strattera.com">www.strattera.com</a>	Capsules, oral	Norepinephrine reuptake inhibitor	Attention deficit/hyperactivity disorder (ADHD)
Eletriptan HBr	Relpax	Pfizer <a href="http://www.relpax.com">www.relpax.com</a>	Tablets, oral	5-HT receptor agonist	Migraine
Eplerenone	Inspira	Searle <a href="http://www.inspra.com">www.inspra.com</a>	Tablets, oral	Aldosterone blocking agent	Hypertension
Ezetimibe	Zetia	Merck and Schering-Plough <a href="http://www.zetia.com">www.zetia.com</a>	Tablets, oral	Cholesterol absorption inhibitor	Hyperlipidemia
Fulvestrant	Faslodex	AstraZeneca <a href="http://www.faslodex.com">www.faslodex.com</a>	Injection	Estrogen receptor antagonist	Breast cancer
Ibritumomab tiuxetan	Zevalin	Idec Pharmaceuticals <a href="http://www.zevalin.com">www.zevalin.com</a>	Injection	Monoclonal antibody/Radiopharmaceutical	Hodgkin's lymphoma (some types)
Icodextrin	Extraneal	Baxter Healthcare <a href="http://www.baxter.com/doctors">www.baxter.com/doctors</a>	Dialysis solution	Dialysis solution	Peritoneal dialysis in chronic renal failure
Interferon beta-1a	Rebif	Serono <a href="http://www.rebif.com">www.rebif.com</a>	Injection	Interferon	Multiple sclerosis
Nitazoxanide	Alinia	Romark <a href="http://www.romark.com">www.romark.com</a>	Suspension, oral	Antiprotozoal agent	Pediatric Diarrhea from some protozoan parasites
Nitisinone	Orfadin	Swedish Orphan <a href="http://www.swedishorphan.com">www.swedishorphan.com</a>	Capsules, oral		Adjunct for hereditary tyrosinemia type 1
Olmесartan medoxomil	Benicar	Sankyo Pharma <a href="http://www.benicar.com">www.benicar.com</a>	Tablets, oral	Angiotensin II receptor blocking agent	Hypertension
Oxaliplatin	Eloxatin	Sanofi-Synthelabo <a href="http://www.eloxatin.com">www.eloxatin.com</a>	Injection	Platinum antineoplastic	Colorectal cancer, in combinations
					...continued—pg. 6

## Alzheimer's—continued from pg 3

duction in Ach correlates with cognitive decline in AD.<sup>6</sup>

So in review, each of these contributing factors 1)  $\beta$ -amyloid plaques, 2) inflammation, 3) decreased cerebral blood flow, 4) NFTs, and 5) Ach influence the pathogenesis of AD. Theoretically, drug therapy targeted at these areas has the potential to prevent or treat AD. Ongoing research has involved the use of HMG CoA reductase inhibitors to target the inflammatory pathway associated with AD.

**TREATMENT**

Although there is no cure for AD, pharmacologic treatment involves managing the cognitive, behavioral, and psychotic symptoms. Agents such as monoamine oxidase inhibitors (i.e. selegiline) and anticholinesterase inhibitors have been used in the treatment of AD.<sup>7,8</sup> The only class with an FDA indication for treatment of the cognitive symptoms of AD, is the anticholinesterase inhibitors. They work to inhibit the degradative metabolism of acetylcholine released by presynaptic neurons. On average these medications only stabilize cognitive function for one year.<sup>9</sup> Marketed products include donepezil (Aricept<sup>®</sup>), rivastigmine (Exelon<sup>®</sup>), and galantamine (Reminyl<sup>®</sup>).<sup>10</sup> Generally, the behavioral symptoms may be managed with selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine (Prozac<sup>®</sup>), citalopram (Celexa<sup>®</sup>), fluvoxamine (Luvox<sup>®</sup>), sertraline (Zoloft<sup>®</sup>), and paroxetine (Paxil<sup>®</sup>). Although atypical antipsychotics are better tolerated, both traditional and atypical antipsychotics have been used in the management of the psychotic symptoms of hallucinations, delusions, agitation, and extreme hostility with moderate efficacy. Examples of atypical antidepressants are risperidone (Risperdal<sup>®</sup>), quetiapine (Seroquel<sup>®</sup>), and olanzapine (Zyprexa<sup>®</sup>). Determining patient specific therapy is important and will depend on drug and disease-state interactions.

In addition to the pharmacologic treatment of symptoms, the use of nonpharmacologic treatment is necessary. It is very important for the family, caregiver, and patient to receive education about AD. Several strategies that caregivers can implement include:<sup>12, 13</sup>

- **Avoid frustration by keeping requests and demands of the patient simple and avoid complex tasks.**

- **Remain calm, firm, and supportive if the patient becomes upset.**

- **Keep the environment consistent and avoid unnecessary changes especially within the living area and daily schedule.**

- **Make scheduled toileting times.**

- **Always provide positive reinforcement.**

Unfortunately, after implementing pharmacologic and nonpharmacologic therapy structural brain changes suggestive of AD may stabilize or continue to occur. As the number of people developing AD continues to grow, so does the cost. This has lead researchers to search for preventative treatments that could be used in a large number of people at risk for AD but who may never have the disease. Several agents have been studied including non-steroidal anti-inflammatory agents (NSAIDs), estrogen, vitamin E, and HMG CoA reductase inhibitors (statins). Data is insufficient to support using NSAIDs for their anti-inflammatory component in the prevention or treatment of AD. In addition, the long-term risks of gastrointestinal side effects outweigh the proposed benefit of NSAIDs.<sup>14</sup> Estrogen levels after menopause have been associated with learning and memory functions. However, in view of the result of the Women's Health Initiative the use of estrogen long-term, needs further clinical evaluation. Presently, no definitive evidence exists to support the use of estrogen in the prevention of AD and current guidelines do not recommend the use of estrogen in the prevention or treatment of AD.<sup>13,15</sup> Vitamin E (1000 IU po bid) has been used to slow the progression of AD due to its antioxidant properties.<sup>13, 16</sup> Finally, statins have been suggested to prevent AD through a mechanism other than cholesterol lowering.

Surprisingly, the mechanism of action of statins in AD is separate from that in hyperlipidemia.

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**STATINS IN AD**

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## Significant New Therapeutic Drugs for 2002, continued

Generic Name	Trade Name	Mfg.	Dose Form	Description	Indications
Pegfilgrastim	Neulasta	Amgen <a href="http://www.neulasta.com">www.neulasta.com</a>	Injection	Biologic/colony stimulating factor	Prevention of infection
Peginterferon alfa-2a	Pegasys	Hoffman-LaRoche <a href="http://www.pegasys.com">www.pegasys.com</a>	Injection	Biologic/ Interferon	Hepatitis C
Rasburicase	Elitek	Sanofi-Synthelabo <a href="http://www.sanofi-synthelabous.com/products">www.sanofi-synthelabous.com/products</a>	Injection	Recombinant Urate oxidase enzyme	Uric acid conc. in children as adjunct to chemotherapy
Sodium oxybate	Xyrem	Orphan Medical <a href="http://www.orphan.com">www.orphan.com</a>	Solution, oral	CNS depressant	Narcolepsy/cataplexy
Tegaserod maleate	Zelnorm	Novartis <a href="http://www.zelnorm.com">www.zelnorm.com</a>	Tablets, oral	5-HT <sub>4</sub> receptor partial agonist	Irritable bowel syndrome in women
Treprostinil sodium	Remodulin	United Therapeutics <a href="http://www.unither.com">www.unither.com</a>	Injection	Vasodilator	Pulmonary arterial hypertension
Voriconazole	Vfend	Pfizer <a href="http://www.vfend.com">www.vfend.com</a>	Tablets, oral	Triazole antifungal	Aspergillosis and other fungal infections

### Web Health Links—continued from pg. 3

ability and Accountability Act (HIPAA) of 1996 has prepared a 25-page “brief” for health care providers, nearly all of whom must now be complying with the rule.

<http://www.hhs.gov/ocr/privacysummary.pdf>

### DEA Updates ‘Drugs of Abuse’

The new edition of “Drugs of Abuse,” covering the Controlled Substances Act and describing narcotics, narcotic-addiction treatment drugs, depressants, stimulants, anorectic drugs, cannabis, hallucinogens, anabolic steroids, and inhalants, was recently published online by the Drug Enforcement Administration. This 71-page document contains a wealth of information on the topic, with many illustrations. <http://www.dea.gov/pubs/abuse/drugsofabuse.pdf>

### Lindane labeling revised

The FDA announced updates to the labeling of Lindane Shampoo and Lindane Lotion on March 28, 2003. These labeling updates are based on the information generated from FDA’s MedWatch program, a voluntary system for reporting side effects to FDA, and reports from medical journals. The new information includes: serious side effects including seizures and deaths have been reported in patients who use too much Lindane or after a second treatment with Lindane; seizures may occur even if Lindane is used as directed. <http://www.fda.gov/cder/drug/infopage/lindane/default.htm>

## Alzheimer's—continued from pg 5

increases constriction of blood vessels and ultimately increases blood flow in the brain.<sup>17</sup> Jick and colleagues reported the results of an epidemiologic, observational, case-control study. Subjects aged 50-89 included from the U.K.-based General Practice Research Database were classified into 3 groups. The first group included patients taking lipid-lowering agents (LLA) within the previous six months, those with a clinical diagnosis of hyperlipidemia and untreated, and a randomly selected group of 25,000 other individuals without record for hyperlipidemia or statin therapy. From this base population 284 cases with dementia or AD and 1080 controls were identified. After logistic regression with adjustments for age, sex, history of coronary bypass surgery and cerebral ischemia, smoking, and body mass index the results indicate that a person on statin therapy had a 71% reduction (RR 0.29 [0.13-0.63]) of risk of developing AD as compared to a patient not taking a statin. However, patients taking other LLA and patients with untreated hyperlipidemia did not have a statistically significant decreased risk, which further supports the role of an alternative mechanism of statins other than decreasing cholesterol.<sup>17</sup>

Another study found that the use of lovastatin and pravastatin reduced the risk of AD by 60-73% (RR 0.36 [0.27-0.40]). It was an epidemiologic, multi-center, cross sectional analysis comparing the prevalence of AD in 3 groups: 1) the entire population, 2) patients on statins, and 3) patients receiving medications for hypertension or cardiovascular disease. Interestingly, with simvastatin a reduction in the prevalence of AD was not found. Likewise, patients taking antihypertensive and cardiovascular medications did not have a decreased risk of developing dementia.<sup>18</sup>

Although these trials have limitations they suggest a potential benefit of HMG CoAs. Because they are observational, a cause-effect relationship cannot be shown and the results need to be confirmed in randomized controlled trials (RCT). There are two ongoing RCTs to examine if there is an effect of HMG-CoA reductase inhibitors on the prevention of AD. **PROSPER: Prospective Study of Pravastatin in the Elderly at Risk** study will evaluate approximately 6,000 individual's response

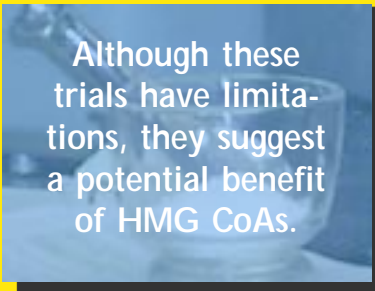
to pravastatin versus placebo taken daily for 3 years with a secondary outcome of the incidence of cognitive decline. The second study is titled: Effect of the HMG-CoA Reductase Inhibitor Atorvastatin Calcium, Lipitor, in the Treatment of Alzheimer's Disease. Since atorvastatin does not cross the blood brain barrier, the objective of this study is to determine if lowering cholesterol concentrations in the blood stream alone will reduce the incidence of AD. This trial is scheduled to end in September 2003.

Is it time for the elderly to demand a prescription for a statin? From these studies we may conclude that it is even more reasonable to provide statin therapy for the prevention of cardiovascular disease to patients with hyperlipidemia and a family history of dementia due to a possible secondary mechanism. It still remains the clinician's decision to treat hyperlipidemia according to the Adult Treatment Panel III guidelines until further evidence supports or refutes the use of statins in the prevention of AD.

As for BR who is living day to day under direct supervision, treatment and preventative options are not available to reverse progression of his disease. However, because he is one of 4 million Americans suffering with AD, researchers will continue to strive to find a cure, more effective treatment, or preventative therapy for AD. Who knows? HMG CoAs may be the agent to surpass current options.

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Although these trials have limitations, they suggest a potential benefit of HMG CoAs.

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