Sanders-Brown Center on Aging
Alzheimer's Disease Research Center

Volunteer News

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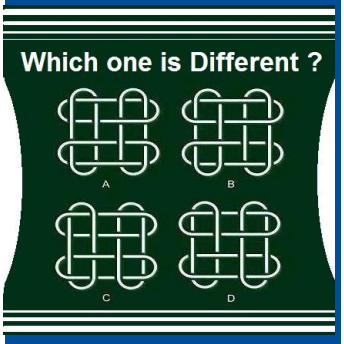
INSIDE THIS EDITION:



Got an idea for the newsletter? Call 859-323-5550

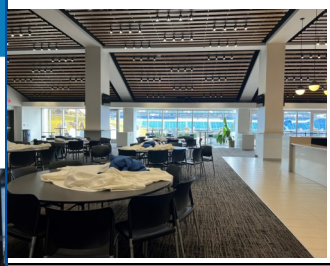
We're finally back in action! & STRONGER TOGETHER!

Please join us for the 15th Annual "Mind Matters" Health Summit this May 8, 2023 from 10am-2pm at Kroger Stadium

Do you want a stronger brain? Do you want to fight back against your future risk for Alzheimer's disease and related disorders? Of course, we all do! And we know that we can do this together, because we are STRONGER TOGETHER and that's the theme of this years "Mind Matters" Health Summit.

It's been a long three years of COVID that has limited our abilities to serve you best through our many community programs. We have all isolated and succeeded in making it through. Of course, we still all grieve those we have lost over this period, but NOW is the time to start anew, stronger than ever & stronger together!

Our "Mind Matters" Health Summit has been one of our strongest community events over the past two decades, modeled after the Children's Explorium, but for those of us that are aging. Hands-on activities and education for your brain health are central to this event, and after a three year hiatus, we're back!



The event this year will be held at the Longship Club at Kroger Stadium on May 8th from 10 am to 2 pm. All events are absolutely free of charge and a complimentary lunch and refreshments are provided for all attendees. The event will include education sessions, classroom style interactive activities, and hands-on activities to help us all keep our brains stronger together! (Cont. on pg 4)

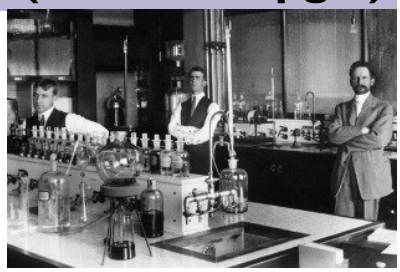
Understanding the FDA drug approval process for new Alzheimer medicines: What is happening now!

Making sense out of the media frenzy, and what this means for all of us?

Over the last two years, you have been hearing about new medicines for Alzheimer's disease undergoing the FDA approval process. Much of the media frenzy has led to significant confusion for many of us. If this sounds like you, and you would like to know more, read on!

Federal regulation of drugs emerged as early as 1848, under a law that addressed only imported drugs. In 1905 the American Medical Association launched a private, voluntary means of controlling a substantial part of the drug marketplace, a system that remained in place for over a half-century. Drug regulation by the FDA has evolved considerably since President Teddy Roosevelt signed the 1906 (Cont. on pg 2)

FDA approval process for new AD medications (cont from pg 1)

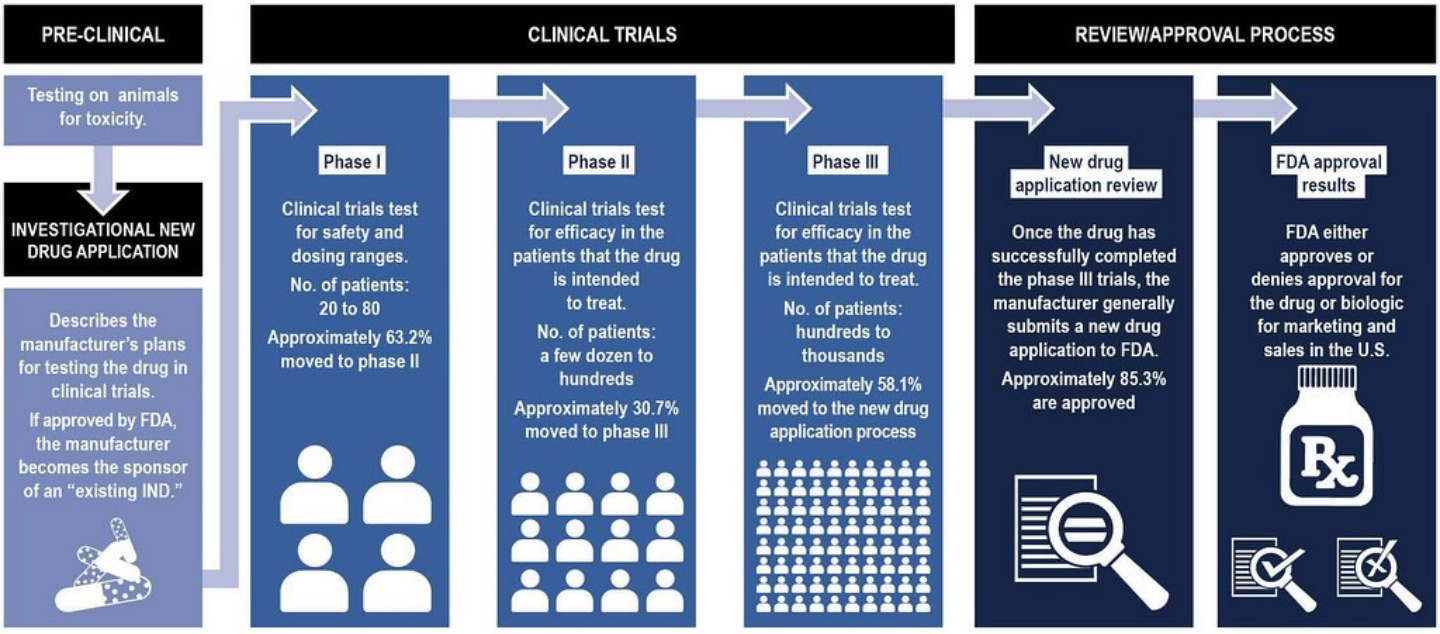


Pure Food and Drugs Act. At the turn of the 20th century, there were no federal regulations to protect the public from dangerous drugs. "It was a menacing marketplace filled with products such as William Radam's Microbe Killer and Benjamin Bye's Soothing Balmy Oils to cure cancer," says John Swann, Ph.D., a historian at the Food and Drug Administration in Rockville, MD. "Products like these were, at minimum, useless remedies that picked the pocket of the user, but they could also be downright harmful." Today, the drug review process in the United States is recognized worldwide as the gold standard. Drugs must undergo a rigorous evaluation of safety, quality, and effectiveness before they can be sold.

FDA Center for Drug Evaluation and Research

"I think the FDA's biggest contribution to health has been through its progress in evidence-based medicine," says Steven Galson, M.D., who has served as director of the FDA's Center for Drug Evaluation and Research (CDER) since July 2005. The CDER serves as the consumer watchdog for the roughly 11,000 drugs on the market. Drugs include prescription and over-the-counter (OTC) medicine, as well as fluoride toothpaste, antiperspirants, dandruff shampoos, and sunscreens. Drugs undergo a complete evaluation of their metabolism, their interactions with other drugs, and potential differences in safety and effectiveness for people of different genders, ages, and races. Along with approving beneficial drugs for marketing, the CDER regulates the manufacturing, labeling, and advertising of prescription drugs.

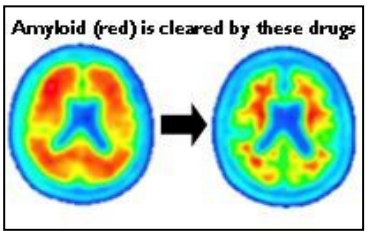
The drug approval process may be too slow for some, but it is designed to protect us all. Every drug has to go through 3 phases of study before approval is granted. Phase I studies are "first in human" and are approved on the basis of animal safety data. They typically have small numbers of human participants that are generally healthy to make sure the drug is safe for humans. If the study is successful, it will move on to Phase II, designed to further ensure safety and find the right dose that might maximally help with minimal harm. Neither Phase I nor II are designed to prove the drug works. If Phase II studies are successful, the drug moves on to Phase III studies to test whether the drug actually works for the disease or condition intended. The FDA oversees and regulates every step of this process to ensure the safety of research participants and the integrity of the studies being done. All U.S. studies must also register their studies through a federal website ***https://clinicaltrials.gov.*** You can search for legitimate clinical trials through this link. The pictograph below illustrates the FDA drug testing and approval process. (Cont. on pg 3)



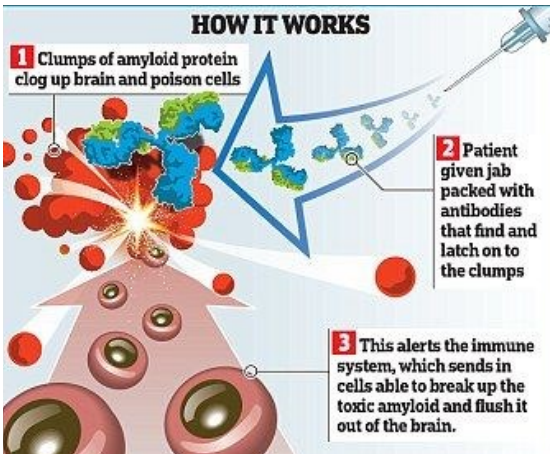
Source: GAO analysis of FDA data and a 2016 collaborative study by Biotechnology Innovation Organization, Biomedtracker, and Amplion.[a] | GAO-17-564

FDA approval process: so where do the AD drugs stand now?

Here at the Sanders-Brown Center on Aging, we have been working on drug studies targeting amyloid plaques in Alzheimer's disease for almost two decades. The process has taken much time but is finally coming to fruition. These drugs are the first potential disease-modifying therapies for this devastating disease, meaning they may actually change the disease itself, leading to a slowing or even potentially one day a cure. Over the past two years, three of these drugs have applied to the FDA for approval based on the studies done. The first, Aduhelm® (aducanumab), received "accelerated" FDA approval in June 2021 based on its ability to remove amyloid plaques from the brains of living AD patients. The second, Leqembi® (lecanumab aka BAN2401), received "accelerated" approval just this year in January 2023. The third, donanemab, did not receive "accelerated" approval by the FDA. Medicare has determined that they will not cover prescriptions, but will only cover research use of these medicines that have "accelerated" approval. But this is confusing, what is the difference between "accelerated" and "full" approval? If they all remove amyloid, aren't they just the same drug? When might they be available to us? And what can we expect in terms of slowing or stopping the disease? These are the questions we can help you understand the answers to!



"Accelerated" approval was granted based on clear demonstrations of amyloid removal from the brain for both Aduhelm® and Leqembi®. Due to trial design differences the FDA did not feel that Donanemab provided enough evidence of amyloid removal to grant even "accelerated" approval. What all of these drugs are seeking is full approval so that they can be prescribed to the millions with Alzheimer's. Full FDA approval requires additional proof of benefit from at least two Phase III trials. As such, Aduhelm® and donanemab have yet to do another trial and look for positive results before the FDA will even consider full approval. Leqembi® already has such data and the FDA is reviewing currently with a potential decision estimated to be forthcoming in June 2023. Most experts in the field believe Leqembi® will receive full approval at that time, and that Medicare will follow suit and grant prescription coverage, but there remain many uncertainties as to timelines and outcomes of this process.

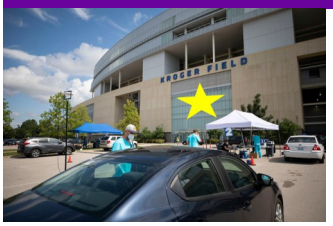


As we have discussed in prior Newsletters, these drugs all target amyloid, but do so in different ways and so they are not all the same drug. Risks and benefits appear to vary widely between such drugs and so it is unclear if all, some, one, or none of these will ever reach full approval status. What is clear is that clinical benefits seem limited to slowing Alzheimer's by about 30%, and that these benefits depend on how effectively amyloid is fully removed from the brain. We are excited to see this new era start, but realize that we still have much work to do. We want to slow or stop Alzheimer's 100% of the way, not just 30%. Do we need to add other drugs, or just remove the amyloid earlier? Answers to these questions are not known, but the AHEAD trial funded by the NIH represents a national effort to explore whether earlier removal may delay or even prevent Alzheimer's disease in persons with normal memory. If you are interested in exploring if the AHEAD study is right for you, please call us at (859) 323-1331.

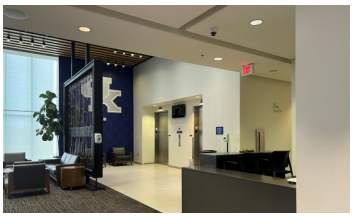
While many uncertainties remain, the one thing you can be certain of is that we will not stop until we find better medicines and an eventual cure for Alzheimer's and all related disorders!

It is a national priority that these drugs be tested in and made available to <u>all</u> persons if approved, especially folks who are less likely to participate in research studies. If you know someone that might benefit from engaging in this research, including your Black, Hispanic, and Appalachian friends and family, please pass on this newsletter and urge them to call us and get involved!

"Mind Matters" Health Summit: STRONGER TOGETHER (Cont from pg 1)



Our new venue in the Longship Club at Kroger Field has abundant parking as close as 20 feet from the main entrance allowing easy access for those with physical disability. Dedicated elevators will bring you right to the Club which is situated overlooking the field at the 50-yard line. The Club is modern, accessible, and a truly beautiful venue for this event.



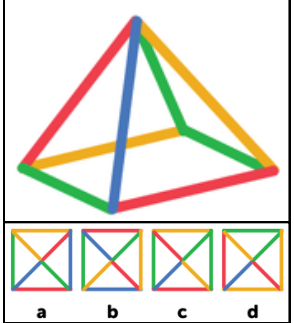
Our focus this year, STRONGER TOGETHER, will educate and engage in ways to keep your brain healthy through free medical screenings, and programs on physical exercise, mental health and well being, art and creativity, among many more. Interactive exhibits can help you maximize your independence and plan for a happy and healthy future.

Learn about the latest discoveries to maximize your brain health from experts in the field. Master stress reduction techniques and learn how to exercise safely no matter your overall physical health and abilities. What you learn and engage in could buy you years of continued independence as we strive to help you make your brain stronger together!

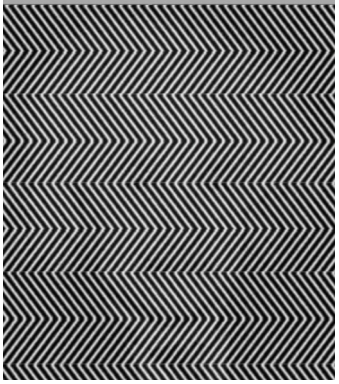
So mark the date on your calendar as you won't want to miss this one. If you have questions or would like to pre-register for the event, please call us now at (859) 323-5550. We can't wait to see you there!

Visual-spatial function can be a sign of impending dementia! Try these visual brain exercises to keep this important brain skill active and healthy!

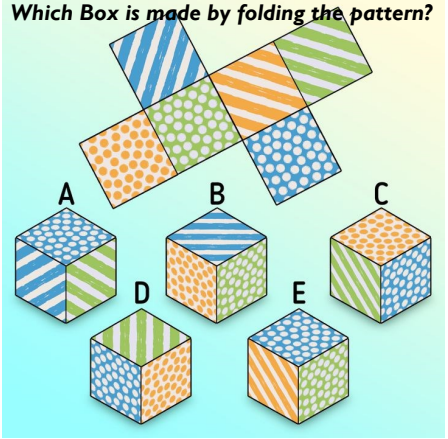
Which is the top view?



Can You Tell the Name of the Hidden Person?



Which Box is made by folding the pattern?



FUN FACTS ABOUT VISION

- *60% of the brain is used for visual processing!*
- *This much of the brain weighs about 720 grams compared to only 15 grams for both eyes together!*
- *Posterior Cortical Atrophy (PCA) is a visual variant of Alzheimer's that often includes Bonnet syndrome with hallucinations*
- *Bonnet syndrome was first described in 1760, almost 150 years before Alzheimer's disease was described!*