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The Biology, Not Politics, Edition

The folks at pharmaceutical companies who set up clinical trials have a big incentive to keep it simple. The more alike everyone is in a drug trial, the more similar the data will be, and the smaller the number of patients required to prove a new drug is safe and effective. But here's the problem: If you only test a new drug on one group (say, young white males), you've only proven the drug works for people like the ones in the trial.

This can have consequences that are not ideal. In the not-too-distant past, for example, artificial heart valves that were developed with only men in the clinical trials did not fit in women's chests. And historically, many clinical trials to treat conditions that primarily affect older adults (such as cancer) excluded patients over 65, despite the fact that those of us who are older metabolize drugs more slowly and often need lower dosages. FDA is charged with protecting the public health and eventually responded to the high rates of adverse events in patients who were not young white males.

FDA Guidance Documents tell industry what the expectations are at the agency. They are first issued as drafts, then go through a lengthy revision process including comments from industry and consumers before they become final. In 2022, when I was working on clinical protocols for new cancer treatments, FDA published a final guidance called "[Inclusion of Older Adults in Cancer Clinical Trials](#)." Up until that time, cancer trials often excluded persons over 65. Finalizing that guidance was an important step forward in protecting public health, and fortunately that guidance is still on the books.

Two years earlier, FDA had published a [draft guidance](#) that said clinical trials of all drugs intended for use by older adults should include them in clinical trials. It was an important next step, and this guidance was in review and on its way to becoming final. But this guidance was cancelled this month, without public review or discussion, and is only available on the Wayback Machine. This Guidance also called for inclusion of members of other

populations such as women and people of color. The name of this guidance was "Enhancing the Diversity of Clinical Trial Populations."

Elimination of this Guidance Document means that folks at pharmaceutical companies who design clinical trials can return to keeping their lives simple by choosing trial participants who are similar to one another. They can, if they wish, select only young white males for trials (unless they are testing a cancer drug, in which case they must include older persons, or at least older males).

Getting rid of this one Guidance Document can be expected to [adversely affect public health](#) over time, as new products are approved based on an unrepresentative subgroup. Pointing this out is not political; it is biological. When clinical trials exclude older persons, or women, or children, or people of color, new drugs may have disproportionate negative effects on people in those groups regardless of whether patients live in red or blue states.

This Guidance is one of the [thousands of documents](#) that was removed from US government websites this month without public notice or discussion. Over time, this one change alone will damage public health if it is not reversed. The combined effect of removing thousands of documents is hard to predict.

Pointing this out is not politics, though it does involve public policy. The same [document](#) that inspired this change calls for other changes that would affect older persons regardless of how, or whether, we voted. These include making Medicare Advantage the [default option](#), allowing removal of [Medicaid coverage](#) for nursing home care, and ending the federal government's ability to [negotiate drug prices](#) with pharmaceutical companies.

FDA Guidance Documents are established with care, with attention to the opinions of those affected, and based on evidence such as rates of adverse events. The elimination of this Guidance did not undergo review and seems to ignore the potential consequences. It was driven by politics, not biology.



All the best,

Stella,

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From the blog this month



The Creative Crone Renaissance

Stella Fosse

We began our lives as scientists and artists, exploring our world and engaging in play. Then school prepared us for that long stretch of years when we worked, cared for others, and kept our home life going. While some of us found creative careers, most of us tamped down our passion to create for decades. All that can change



In Praise of Older Romance

Lisa Harris

One of the reasons I write romances with protagonists in their sixties is to debunk the myth that the older we grow the less alive we are. I understand this presumption because when I was in my twenties—back when I knew *everything* with a certainty real life has since erased—I was sure that people in their sixties had already

with a creative Renaissance in our sixties.

Why Create in Our Sixties?

Why is it beneficial to return to creativity? Because being creative is natural to humans. We thrive on it. Thinking outside the box invigorates our brains. We engage with multiple neural pathways that lie fallow when we focus on logic. Plus, creative pursuits reduce stress, whether we engage in music, visual arts, writing, or dance. And, too, creating gives us more energy, more enthusiasm, as we find novel ways to solve creative problems, whether we make jewelry or structure the plot of a story.

As we create new things we also generate our own sense of purpose. When we are in flow, there is neither time nor reason to question why we are here. Creativity is a force within each of us that adds to the vibrancy of everyday life.

Research shows that being creative also helps us live longer, healthier, happier lives. And when we are creative through movement, as when we dance, we gain the benefits of both movement and creativity.

lived their best years and were headed downhill. Like, they'd raised their families and what did they have left?

I blush at my complete ignorance of the fact that our sixties are some of the most vibrant years a human can live. How do I know that? Because I'm in the middle of them right now. Many of my friends are too, and we're all living our lives completely and fully in these older bodies of ours. My younger self had no concept of the wonder and richness decades of experiences and learning, loving, and being loved would add to our later years.

She also had no idea that romance is alive and well in our sixties and beyond. Why would it not be? We're the same people we've always been. Yes, maybe our sex drive is more tempered, but being turned on feels the same as it always did—fun. Exciting. Definitely still happening. So why don't younger people understand that?

I think this gap is due to multiple factors, among them cultural misunderstandings perpetuated by the media. The bulk of movies and shows portray romantic interest and sexual intimacy as the domain of young people, who then struggle to imagine emotional and physical

Creativity also encourages social engagement—another way to enhance healthspan and lifespan. Writing groups, artist collectives, or just gathering in the hot tub at the gym after dance class are all ways to connect with people with similar creative passions.

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connection beyond their own immediate experience. Hence the pervasive myth that passion dies with age, rather than transforms and deepens.

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Stella Fosse



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