

SAGE CROSSROADS
Interview with Dr. William Evans
Pharmaceuticals and Aging

KYLE JENSEN: Welcome to SAGE Crossroads, the premier online forum on the issues of human aging. These podcasts feature lively discussion with the experts on the ethical, political, economic, scientific, and societal implications of aging related science. Thank you for listening.

I'm joined now with Dr. William Evans. Dr. Evans is the director of the Nutrition, Metabolism, and Exercise Laboratory at the Donald W. Reynolds Institute on Aging at the University of Arkansas for the Medical Sciences.

Dr. Evans, how does government policy impact how pharmaceutical companies develop drugs to target the symptoms of aging?

WILLIAM EVANS: Well, you know, I think government policy obviously has a lot to do with how the FDA thinks about the development of drugs and their impact. I think that things have changed a lot, certainly in the last couple of years, in how the FDA thinks about new drugs, particularly in my area, for older people. You know there are a number of promising therapies for frailty and weakness, but one of the big issues for older people already taking many drugs to control chronic diseases is that however positive a drug maybe, it may have an impact on their overall health.

KYLE JENSEN: So what do you think is wrong with the current regulatory policies?

WILLIAM EVANS: Well, I don't know that there is anything wrong with it. I think that perhaps there has been a little bit of over reaction to some of the problems related to certain drugs that has caused a real caution for a lot of drugs, but at the present time, I'm not sure there is a huge problem right now. I think that everybody needs to proceed with a little bit of caution that a drug that may be used for an at risk population is safe to take over a long period of time, and that's going to be a pretty high bar for older people, but I think that it's an important thing to consider.

KYLE JENSEN: Well, what's a condition as an example that you think could be treatable with drugs but...

WILLIAM EVANS: One of the conditions that we are thinking about is something that's called sarcopenia. Sarcopenia is the age associated loss of muscle mass that occurs in all of us but is highly prevalent in older people. Loss of muscle mass leads to increased amount of disability, chronic disease, and costs a tremendous amount of money to the health care system. At the present time, the FDA hasn't recognized sarcopenia as a treatable indication although there are signs that they maybe considering that. There are potentially a number of drugs that are specifically in the pipeline right now to treat frailty and muscle weakness in older people. Some of those drugs are the new generation of what are called SARMS or selective androgen receptor modulators. There are a number

of pharma companies that have anti-myostatin drugs that has whole grade promise to improve muscle mass. Even a brand new...there was an article published just this week looking at a grellin memetic which is a hormone that stimulates the production of growth hormone, showing some really positive effects in older people.

KYLE JENSEN: Now is getting the FDA to recognize these conditions, is this just a matter of lobbying them to expand their horizons or is there a better way to approach it?

WILLIAM EVANS: Exactly. I think there are a number of ways to approach it. One is to lobby. It is clear that public pressure helps to make the FDA think about some of these issues. I think that we are working with some of the professional societies like the Geriatric Society of America to also come to some agreement and consensus. Also what the FDA, I think, really likes to see with regard with potential new indications is not just consensus from the scientific community but also consensus from professional organizations, and I think that we are working towards that right now.

KYLE JENSEN: So do you see much hope in the next 5 years of getting some of these regulations changed?

WILLIAM EVANS: I see great hope. We've had a number of meetings with the FDA already and it's been a real good give and take. I think that they recognize that there is a problem out there and that there are potential therapies. What they are concerned with, appropriately, is drugs like these may have the effect of being used in a very large number of people. Obviously the number of older people with weakness and low muscle mass is enormous, and so potentially we have older people taking these drugs for a very long time, so I think we have to be very concerned about not just efficacy but safety.

KYLE JENSEN: Lastly, the audience of SAGE Crossroads is made up of scientists, policy makers, and curious consumers. If there is one last statement you would like to make to them about the development of drugs to target symptoms of aging, what would it be?

WILLIAM EVANS: Well...I think that we are about to see a revolution in how we treat muscle problems that may result in weakness and increase mortality. It's not just aging; there is a new generation of drugs that treat muscle wasting that maybe secondary to cancer or heart failure or renal failure. I think there's a lot of reason to be optimistic. There is a new generation of drugs that look to be very effective and extraordinarily safe, so I think there is a lot of reason to be optimistic.

KYLE JENSEN: On behalf of SAGE Crossroads, I'm Kyle Jensen.