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Doctor Honoris Causa:

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I want to start by expressing my Thank You to His Most Excellent and Magnificent Rector of the Miguel Hernández University of Elche, the authorities and members of the university governing body, the faculty and the research personnel and administrative and service staff, students, ladies, gentlemen, and Friends.

I would like to express my sincere gratitude towards the Miguel Hernández University for conferring me this Doctor Honoris Causa, with special thanks to the School of Pharmacy and the Department of Engineering of Elche for nominating and supporting this Doctor Honoris Causa on behalf of this university. I offer a very special thank you to my colleague, collaborator and friend for the past 15 years Dr. Marival Bermejo for her dedication in assembling this nomination. This appreciation also extends to all colleagues at various international institutions who supported this nomination including the UMH departments.

I must start by saying that this honorary degree from UMH, a foreign institution, most notably a Spanish Institution, is particularly significant to me because it signifies accomplishment in two very different ways; one is the significant recognition of my pharmaceutical scientific contributions on an international scale, the second is more specific to my ambition to extend the impact of my vision of biopharmaceutical science and pharmaceutical product regulatory science to the Spanish speaking world, especially South America. This was my distant vision (very distant) when I first met Dr. Marival Bermejo 15 years ago at a Santiago de Compostela Pharmaceutical meeting. I went to her poster

presentation, the one of most interest to me, discussed the poster on drug absorption with her students, and the rest is history. We have had a very collaborative and enjoyable relationship ever since, most notably teaching biopharmaceutics in Latin American countries and regulatory organizations. Our many workshops in Latin America over the past 15 years have been one of my most enjoyable professional experiences. Thank you again Marival for coming to my laboratory in 1999 and taking up this challenge.

The evolution of Pharmaceutical Sciences over the past 55 years has been revolutionary; my first contact with pharmacy was 1959. I had the good fortune and serendipity of entering a rapidly expanding Pharmacy field, the pharmaceutical sciences. The enormous post WW II expansion of the pharmaceutical Industry, (remember, penicillin was developed in the 1940's by the pharmaceutical industry), had reduced the role of the community pharmacist to almost a "count and pour-lick and stick" job, while the role of pharmaceutical science in industry exploded along with the industry. I recall one of my first activities in pharmaceutical science was the science of chemical degradation and expiration dating. It is hard for me to think that this product expiration date, so pervasive today, is only about 40 years old. The food industry uses 'freshness date' or 'sell by date'...much more creatively than the pharmaceutical industry! I published a book on "Chemical Stability of Pharmaceuticals 2nd edition" in 1986, and it is still in print. At that time, in the 1980s, I was switching my research field to biopharmaceutics, particularly oral biopharmaceutics and have remained in that fertile field ever since.

You may ask; "How Did I Get There"?...In parallel to my work in Chemical Stability work I was working on alpha-chymotrypsin, a gastrointestinal digestive enzyme, crystallized and structure determined in the 1960's (a physical chemistry study) and most significantly, it turns out, studying physiology of the gastrointestinal tract. I was also attending Chemical Engineering lectures as a "visitor". Yes, I was still going to school when I was a faculty member at the University of Wisconsin. I had realized that the gastrointestinal tract was a tubular chemical reactor and I understood that chemical engineering science, and in particular transport phenomena and chemical reactor theory, had much to contribute to this largely neglected oral science field. There I found my true scientific 'life' - yes...at about age 35. My subsequent scientific advances, most notably the Biopharmaceutics Classification System (BCS), first published in 1995, were based on this continued schooling!

I must also add that BCS was the result of another serendipitous event, which was that of being asked to serve as an opponent of the PhD exam of Hans Lennernäs in 1992. Hans had developed a methodology for determining intestinal permeability in humans, based on our work in the rat Animal model. We subsequently collaborated for many years and the human permeability data, obtained with Han's human permeability system, was essential to obtaining the regulatory (FDA) approval of the BCS bioequivalence standards for oral drug products. This standard has been accepted and extended by the EMA and WHO.

In 1990 I spent one year on a sabbatical at the FDA. My colleagues thought I should have gone to Europe, but in fact my FDA experience was one of the most valuable in my career, second only to working with the Chemical Engineers at the University of Wisconsin. That sabbatical and my relationship with the FDA resulted in a subsequent deep interest in the scientific basis for pharmaceutical drug product standards insuring efficacy of drug products. After all, the patient receives a product not a drug. Our whole health care system depends on products providing the therapeutic efficacy stated on the label, based on Phase III and subsequent clinical studies. How we maintain and evolve those standards over time is a scientific question of profound importance to the health of our society and the functioning of the world's health care system. The scientific evolution of those standards has become a primary focus of my career. My scientific thinking has led me to focus on oral drug products, the most commonly used pharmaceutical products, and to specifically focus on product *in vivo* performance, particularly dissolution in the gastrointestinal tract.

Dissolution of oral drug products, in particular, has been a standard for 50 years. That standard has evolved only slightly over the past 50 years and the focus has been on the *in vitro* methodology, not the *in vivo* processes actually controlling product therapeutic performance. My late-stage career goal has thus become one to promote dissolution to a higher recognition of its importance. This involves not only developing the science, but convincing the scientific community of the importance of doing the science and evolving this dissolution standard to an *in vivo* predictive dissolution (IPD). This involves the significantly larger process of change involving diverse scientists and organizations that have become 'entrenched' (this may sound like too strong a word, but it's appropriate) in a way of doing things that must change in the 21st century. My hope is that through the network of International scientists and friends that I have maintained over the course of my career I can initiate this process of change that will continue for many decades into the future.

If my story has a deeper meaning, it is to keep learning, keep going to school, find that enjoyable space in you that is deeply satisfying, find a way to make enjoyable what you have to do to make a living... and keep at it... slow is ok.

I will end by revealing what my wife, Pamela, who could not make this trip because of the attention she has to give to our (4) grandchildren at this time...says about me..."I am slow but trainable". I am proud to be trainable, to have learned throughout my life from many colleagues, friends and my particular friendship with Dr. Marival Bermejo who has contributed so much to expanding BCS to the world. I learned ...not only hard (science) skills...but the 'soft' skills in life. We need both.

Let me end by saying once again how honored I am in receiving this Doctor Honoris Causa from Miguel Hernandez University, thank you again to all of my colleagues who contributed to supporting this award for me, and especially to Dr. Marival Bermejo.