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**Orally delivered subunit vaccines: A tool to increase the immune response, increase compliance, eliminate the cold chain and lower the cost of immunizations**

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An orally delivered and heat-stable subunit vaccine can eliminate the cold chain, needles, and skilled personnel to deliver the injections. This can lead to a low-cost, convenient method of immunization with higher compliance and a reduction, if not elimination, of disease. Many approaches have shown proof-of-principle yet an oral vaccine has remained an elusive goal due to many practical problems that hamper commercialization. These include a subpar immune response, the need for high levels of antigen to overcome the natural digestion process, and the inability to scale-up and stockpile antigens due to instability at ambient temperatures. We have developed a platform that can overcome these barriers by first accumulating the antigen in maize grain orders-of-magnitude higher than reported in other systems. Next, novel methods for processing using a supercritical fluid extractor (SFE) further enhanced the immune response and impart greater heat stability. The resultant material is then formulated into tablets with a precise dosage suitable for oral delivery. Using hepatitis B surface antigen (HBsAg) as the lead candidate, a robust immune response has been demonstrated in sera as well as tissues that do not respond to the parenterally administered antigen. This provides a new tool for increased efficacy, lower cost, cold chain-independence and a more convenient vaccine. The additional strong mucosal response may provide greater protection for pathogens that enter through the mucosal system which account for the vast majority of diseases. In addition to the HBsAg lead candidate, other vaccine candidates will be discussed that demonstrate the breadth of the platform.

**Biography**

Dr. Howard completed his Ph.D. in Biochemistry at the University of California at Riverside. He went on to establish and lead the efforts of biotechnology groups at two Fortune 500 companies and later founded a start-up biotechnology company. For the past 10+ years, he has been the President of ABI, a biotechnology company focused on developing novel products for human and animal health products. He is the author or inventor on more than 150 papers and patents

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