LETTER

Albumin from rice: Why and wherefore?

The work by He et al. (1) expressed concern that human albumin derived from plasma fractionation is associated with "an increasing public health concern with plasma-derived HAS with its potential risk for transmission of infectious pathogens such as hepatitis and HIV" (1). The work by He et al. (1) offered two references to support this statement, one of which included the unequivocal statement that "[b]oth HSA and PPF are manufactured with pasteurization procedures that have led to an excellent viral safety record based on 50 years of clinical use" (2). The other reference does not mention albumin but describes emerging pathogens in the context of blood safety. We note that none of the agents noted, in addition to mainstream transfusion-transmitted agents, have ever been transmitted by albumin. This aspect of albumin's safety derives from its robust purification and pathogen clearance processes, which have proven reliable against the threat of known and unknown pathogens. Albumin's safety in other aspects is also high (3). Much of this safety is because of the establishment of good manufacturing practices overseen by regulatory agencies. The required features of such practices for plant-derived pharmaceuticals have been reviewed (4), and we suggest that the introduction and enforcement of such measures is crucial for all manufacturing processes, including the measures described in the work by He et al. (1). We note the interest of He et al. (1) in cost-effectiveness and their assertion that this cost-effectiveness can be deduced for their process from the level of protein expression achieved; however, it seems that the manifold safety measures needed to achieve environmental protection as described in addition to factors not mentioned have not been factored into this nonquantified estimation. Consideration of the measures described in the work by Howard and Hood (5) may contribute to a more concrete assessment of the facility by which the process in the work by He et al. (1) may be developed into a therapeutic product.

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5. Howard J, Hood E (2007) Methods for growing nonfood products in transgenic plants. *Crop Sci* 47:1255–1262.

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