

**Abstract** In recent years, the biopharmaceutical industry has seen an increase in the development of so-called orphan drugs for the treatment of rare and neglected diseases. This increase has been spurred on by legislation in the United States, Europe, and elsewhere designed to promote orphan drug development. In this article, we examine the drivers of corporate social responsibility (CSR) activities in orphan drug markets and the extent to which biopharmaceutical firms engage in these activities with a strategic orientation. The unique context of orphan drugs constitutes a research opportunity to test the applicability of existing theoretical perspectives on CSR and strategic CSR. Using Schwartz and Carroll's (Bus Ethics Q, 13(4):503–530, 2003) three-domain approach to CSR and the literature on strategic CSR as a theoretical background, we employ a combination of semi-structured interviews and a quantitative website content analysis to study practices of biopharmaceutical firms in the United States and European Union. Our findings show that both US- and EU-based companies engaged in orphan drugs development perceive their involvement as a responsible business activity beyond the economic dimension of CSR. However, for the majority of these companies their CSR activities do not qualify as strategic according to the criteria established in the literature. We also find significant differences between larger and smaller firms in their use of CSR. Based on these findings, we make several suggestions regarding orphan drug legislation and other measures that might help firms exploit strategic CSR benefits.

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- Authors
- Olga Bruyaka, Department of Management, Virginia Tech, 2007 Pamplin Hall, Blacksburg, VA 24061, USA
- Hanko K. Zeitzmann, Department of Management, Virginia Tech, 2007 Pamplin Hall, Blacksburg, VA 24061, USA
- Isabelle Chalamon, Department of Marketing, Inseec Business School, 21, Rue Alsace Lorraine, 69001 Lyon, France
- Richard E. Wokutch, Department of Management, Virginia Tech, 2007 Pamplin Hall, Blacksburg, VA 24061, USA
- Pooja Thakur, Department of Management, Virginia Tech, 2007 Pamplin Hall, Blacksburg, VA 24061, USA

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