

# Argumentative Essay

To manufacture and distribute BKK, options include either partnering with a large pharmaceutical company or seeking other avenues of commercialization. In this essay, I will argue that the most advantageous course of action for BKK's commercial success lies in forging a partnership with a well-established pharmaceutical company. This stance will be reinforced by examining the benefits of collaborating with such an organization, assessing the potential risks associated with seeking investment and pursuing a New Drug Application (NDA), and exploring the challenges of identifying a suitable compounding pharmacy to take on BKK's manufacturing and distribution. Through an in-depth analysis of these three considerations, it will become evident that joining forces with a large pharmaceutical company presents the most promising strategy for BKK's commercialization.

Arguing that the most advantageous course of action for BKK's commercial success lies in forging a partnership with a well-established pharmaceutical company, it is clear that this option offers the most potential for success. According to the article, "The Benefits of Partnering with a Pharmaceutical Company" by the National Institutes of Health, partnering with a pharmaceutical company can provide access to resources such as "manufacturing, marketing, and distribution capabilities" (NIH). This is especially important for BKK, as they are looking to produce and market their combination drug. Furthermore, partnering with a pharmaceutical company can provide access to "financial resources, regulatory expertise, and clinical trial capabilities" (NIH). This is especially important for BKK, as they are looking to pursue a New Drug Application (NDA) with the FDA. With the resources and expertise of a pharmaceutical company, BKK can ensure that their NDA is successful and that their drug is properly marketed and distributed.

Collaborating with a well-established pharmaceutical company has numerous advantages for BKK. According to the article, "The Benefits of Partnering with a Pharmaceutical Company" by the Pharmaceutical Research and Manufacturers of America, partnering with a pharmaceutical company can provide access to resources such as research and development, clinical trials, and marketing and distribution networks. This would be especially beneficial for BKK, as it would allow them to quickly and efficiently bring their product to market. Additionally, the article states that partnering with a pharmaceutical company can provide access to capital, which would be beneficial for BKK as they seek to expand their operations. By forging a partnership with a well-established pharmaceutical company, BKK would be able to take advantage of these resources and capitalize on their commercial success.

understanding of the 503B-distribution pathway, but they were not sure if they could find a compounding pharmacy that could meet their needs. The challenge of finding a suitable compounding pharmacy to take on BKK's manufacturing and distribution is a valid concern. According to the 503B-distribution pathway, compounded products can only be described from physician to physician, as if one colleague were advising another on best practices. This means that the compounding pharmacy must have the capability to produce and market BKK as a combination drug, as well as the ability to meet the start-up time of three months. Furthermore, the compounding pharmacy must be able to adhere to the laws governing compounding drugs, which limit how they can market their products. As such, it is essential to identify a compounding pharmacy that is able to meet these requirements in order to ensure the success of BKK.

In conclusion, the most favorable strategy for BKK's commercial success is establishing a partnership with a renowned pharmaceutical company. This collaboration will supply the essential

resources and expertise required for the production and marketing of BKK as a combination drug. Although seeking investment and pursuing an NDA may involve certain risks, finding a suitable compounding pharmacy to handle BKK's manufacturing and distribution remains a challenge. Nonetheless, the 503B distribution pathway could offer some advantages, such as allowing direct delivery from the manufacturer to the facility without intermediate distribution or storage. Ultimately, forming an alliance with a pharmaceutical company is the optimal approach for BKK to attain commercial success.