

Spin-Off from University: Opportunities and Challenges to Participate in the Pharmaceutical Industry Development Strategy in Vietnam

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Abstract:- Many studies present solutions to promote spin-off development from universities along with the dynamism of industries in the 4th industrial revolution. Identifying spin-off characteristics from universities that support the development strategy of specific sectors has not been widely considered and researched. This study focuses on the characteristics of spin-offs from universities that support Vietnam's pharmaceutical industry development strategy. The study examines and analyzes the following contents: spin-offs from universities in the innovation ecosystem; participation in supporting human resource development, and the pharmaceutical industry's development. This study combines some of the most important theoretical and conceptual references, systematized from reviewing and referencing documents on spin-offs from universities through a qualitative process of methodological aspects in the form of documents. Key results provide a spin-off model with stakeholders connecting the pharmaceutical supply chain. The study's findings and interpretation are linked to the development strategy of the Vietnamese pharmaceutical industry landscape, calling for the adoption of a more complete perspective on spin-off from university participation in the pharmaceutical industry.

Keywords:- University Spin-Off; Entrepreneurial University; Technology Transfer; Pharmaceutical Sector; Pharma 4.0.

I. INTRODUCTION

In recent decades, the role of universities has expanded to include increased collaboration with industry. For so-called entrepreneurial universities, there is an emphasis on academic knowledge being used more effectively as a source of creativity and innovation in specific sectors [1]. The spin-off model (university spin-off company or technology spin-off) is very popular in developed countries. Establishing scientist-owned startups with their research facilities is a way to both enable the commercialization of technology and help scientists gain long-term benefits from owning assets. Their intelligence and the research institution also benefit economically [2].

Universities and research institutes will form certain research products through scientific research and technological development activities. One of the output products of scientific research is new technologies that can be applied to life, bringing economic benefits to both societies and researchers. Some of these products are patentable, but many require further research and development before commercialization, such as granting universities and research institutes intellectual property rights and allowing them to be commercialized. Governments worldwide are trying to accelerate the conversion of their intellectual property into production processes and industrial products, strengthening cooperation between universities, research institutes, and enterprises [2].

In Vietnam, about 237 universities and about 32 universities offer training in medicine and pharmacy. The number of startups in universities is increasing, while investment capital for startups is also growing rapidly. According to the National Department of Technology Enterprise and Trade Development, Vietnam has about 3,800 startups. Vietnamese startups have attracted investment of more than 1.3 billion USD in 2021, double 4 times compared to last year. Many solutions to promote startups have been recently researched, while solutions to promote spin-off businesses have not received much attention or research. Building a startup university requires an effective innovation ecosystem in which technology transfer services at universities are particularly important [3]. Spin-off and startup are two startup models of interest today, are quite popular, and are growing strongly. In Vietnam, many universities currently offer training in medicine and pharmacy. Spin-offs from universities are not yet of interest and popularity, especially spin-offs related to the pharmaceutical field[2].

Information and data from previous studies show that universities and research institutes are extremely rich. Potential sources of intellectual property, but scientific research results show that this "resource" has not yet been commensurate with available intellectual human resources, especially in the pharmaceutical field in Vietnam[4]. Therefore, research activities such as technology transfer activities and commercialization of scientific research results in fields from universities to businesses need an intermediary model, especially in the pharmaceutical field. This model

helps effectively connect and exploit the rich potential of universities and research institutes, increasing the nation's research capacity and developing the healthcare sector[2].

Vietnam is in the process of international integration, with policies to develop the pharmaceutical industry and university development[5, 6]. The author sees the need for the spin-off to act as an intermediary between higher education and the pharmaceutical industry in scientific research and innovation activities for the pharmaceutical industry development strategy in Vietnam. The objectives of this study are: (i) conduct an overview analysis of issues of concern for a spin-off from a university connecting the pharmaceutical supply chain; (ii) Find the basic characteristics of a university spin-off in the pharmaceutical field; (iii) discuss the results of research on model spin-offs of pharmacy sector enterprise ecosystem; (iv) implications of research with the spin-off model serving as an intermediary connecting research results from universities and the pharmaceutical supply chain. Research findings are the basis for establishing spin-offs as an important stakeholder in implementing Vietnam's pharmaceutical industry development strategy. Collaboration between different organizations is crucial in the pharmaceutical sector to sustainably create new innovative medicines and pharmaceutical services across pharmaceutical supply chain operations.

II. LITERATURE REVIEWS

The university's role in the 21st century is changing rapidly, reflecting a growing interest in the commercialization of university knowledge by scholars and policymakers[3]. Spin-off models are formed in developed industrial countries, originating from universities (separate from activities independent of the university)[2]. University spin-off projects represent a knowledge commercialization mechanism that is attracting significant attention because they have the potential to (a) enhance local economic development, (b) support universities in their core mission of teaching and research and (c) generate high profits for efficient companies[7]. However, it is necessary to carry out tripartite cooperation between universities and businesses and governance in this field. This is how an innovation ecosystem should be built[3].

A. Spin-Off from University in the Innovation Ecosystem

➤ The Foundation for Forming the Spin-Off

The term “Spin-off” means a new company from a parent organization. Often, an employee (or employees) leaves the parent organization, taking a technology that serves as the new company's entry ticket into the tech industry[8]. A spin-off can also involve internal entrepreneurs of an existing organization who establish their startups. The new company maintains a relationship with the parent organization, resulting in a new subsidiary venture.”[9].

Universities and other research organizations always pay more attention to technology transfer mechanisms to establish cooperation between university and enterprise research. Although very different in method and purpose, these alliances often prove successful for both industries in achieving competitiveness, technological advancement, and universities utilizing their resources. Abundant intellectual property is available to fund research and train its students by making them more competitive and prepared for the industrial world[10].

An important aspect that must be approached is the composition of the research team, the founders of the spin-off. They influence future spin-offs in the market. A spin-off is always conceived as a new company founded by individuals who are university employees and whose core technology is transferred from those universities[11]. Leaders are also more likely than their followers to have extensive learning experiences and thus have better access to opportunities. Studies have mentioned other (related) first-mover advantages of creating uniqueness in the market, using conversion costs to lock in sales; establishing exclusive distribution channels; defining standards for new technology; patent guarantee; and controlling other scarce resources critical to competitive success. However, the first mover's strategy also has a smaller risk of success than the follower's. If a company gets in early, it may not be able to recover its initial investment before competitors imitate the product and perhaps even improve upon it. In addition, first movers may miss opportunities obscured by technological and market uncertainties, from which late movers could take advantage. Overall, the findings from the literature show that first movers often do not conclude the net benefits of their strategies, as these benefits depend on many industry-specific factors and companies [12].

➤ Spin-Off Resources

Identifying spin-off's strategic resources and distinguishing them from other common resources is an important basis for effectively allocating, creating, and using them during strategy implementation. The key goal of resource analysis is not only to evaluate the types of assets of the Spin-off but also to understand the potential of resources to create competitive advantage before building and allocating resources and capabilities to Implement new business systems and integrate new business systems into the spin-off's development strategy[11]. Spin-offs always face challenges such as limitations related to business experience, limited market access, advanced technology risks, and difficulties accessing financial resources[13]. Spin-offs need capital for all their activities, so they need other investments, possibly from their own money or calling on other investors[2]. Spin-offs often encounter difficulties accessing financial resources from banks due to the risk of the technology they want to bring to the market. However, loans, especially long-term ones, are the foundation for long-term stability and growth[13].

Spin-offs from universities associated with brands have huge impacts. Because brands have become one of today's most important intangible resources. The brand's value represents the university's reputation in the economy and society and can be associated with the spin-off or the spin-off's brand. University spin-offs rely on the support of employees, customers, investors, and the government to develop them. Besides, technological know-how is an intangible asset whose value is not clearly shown on the balance sheet of most Spin-offs but is increasingly becoming a decisive resource. Intellectual property rights - patents, copyrights, and business secrets are legally protected resources. This is the strength of spin-offs and universities that have spin-offs. The advantage of operating in a university environment, being close to scientists, and even being developed based on scientific research results and creative ideas from university activities is a resource. to develop spin-off[11].

➤ *Spin-Off Strategy*

The spin-off development strategy carries with it the goal of concretizing the mission, development philosophy, and orientation of the spin-off, which are directly related to new business opportunities. The role of the university's spin-off is to create a foundation to identify areas for developing business projects linked to the university's overall development strategy [11]. Spin-offs are especially important in academic entrepreneurship, developing basic research technologies that are not yet popular with established companies due to lower profitability or lack of available markets. The gap between university research and commercialized industrial research can be reduced through spin-offs. Furthermore, spin-offs bring economic and social benefits, including job creation, especially for highly educated graduates, and strengthening the local economy. Spin-off means creating a new business unit by abandoning their previous activities in an existing company or other organization, e.g., (university, laboratory research, etc.)[10].

Spin-off's development strategy depends and is strongly influenced by the founders' will and the university environment in which it was formed[11]. The key universities that create spin-offs are often presented in reports related to university ranking activities and the type and size of the university. Since spin-offs are often founded by academics and faculty members with full-time university contracts, research excellence is closely tied to the spin-off's high qualifications. Several studies show a clear connection between the type of university, the university's ranking, and the number of spin-offs [14].

➤ *Constructive Policies and Support from the Government*

A spin-off from a university is an organization based at a university that conducts academic research of an interdisciplinary nature, often with financial support from government agencies, private companies, and other organizations outside the university. Spin-offs are a unique form of university organization in several respects: (i) they are multidisciplinary, drawing on expertise from several university departments, and (ii) they are boundary markers, facilitating a flow of information and other resources

between the boundaries of the university and the environment of the related professional world[8].

A spin-off represents more or less a temporary system intended to provide flexibility to respond to external influences on a university that require special behavior by the parties involved: government and society. A number of studies have identified the undeniable fact that universities will face difficulties without direct government support policies during the implementation stages, allowing universities to be autonomous and independent. When investing in projects with outside businesses, business development activities will begin to be strongly promoted[11]. To encourage development spin-off from universities, government institutions, and policies need to be synchronized with regard to creation and support functions. Practice shows that the spin-off model is one of the best ways to demonstrate the effectiveness of intellectual property exploitation by training and research institutions[2]. The government needs to promote policies related to technology transfer, patent registration, coordination mechanisms between parties, good practice mechanisms in public-private cooperation, etc. Form and support the activities of university enterprises or are formed thanks to scientific research achievements from the university[11].

B. Spin-offs from universities support human resource development

➤ *Participate in Entrepreneurship Education*

Today, in the period of the 4th Industrial Revolution. Universities have a mission to innovate and create new values thanks to the space of innovation, connecting everything, transdisciplinary, and learning everywhere. University products at this time develop entrepreneurs and entrepreneurs associated with innovation. The organizational model has changed, the university has become diverse in its methods of operation, and internal links and parties have become an ecosystem of "innovative startup universities" to promote the commercialization of products[11].

Entrepreneurship education is becoming increasingly action-oriented, emphasizing learning by doing and activities in group settings[15]. Spin-offs from universities are created to commercially exploit knowledge, technology or research results developed within the university. Other definitions emphasize the relationship with the university through individuals, specifically students, graduates, and staff[12]. Some studies show that in the process of forming and developing spin-offs in universities, they always start from the stage of self-change and integrate training programs, scientific research, and rehabilitation activities. Community service with stakeholders' requirements, especially the government, industries, and businesses. Because they are not only stakeholders using human resources, knowledge, and technology but also investment partners who jointly operate value-creating activities[11]. Expanding the concept of Pharmaceutical Industry 4.0 from just the manufacturer to the entire pharmaceutical supply chain includes several other challenges such as additional human involvement, end-to-end collaboration, sustainability issues, safety and disastrous

consequences if any errors are made, etc[16]. Scholars, policymakers and pharmaceutical industry representatives across the globe are regularly called upon to work together to enhance pharmacists' capacity to meet society's growing needs [17].

➤ *Develop an Entrepreneurial Spirit*

For universities, in the context of increasingly closer links with markets and businesses, many studies have shown the impacts of this link, the effect of "enterprise" thinking, "enterprise" management (enterprise university model) for financial resources, to the application of enterprise principles in the university management and operation model. From the need to cooperate with businesses over the past decades, today universities stop at cooperation in research and development and academic exchange and proactively disseminate knowledge to serve customers, lifelong learning society, especially implementing commercialization of research results and business development[16].

The entrepreneurial spirit in a specific organization, such as a university depends on many factors. Studies refer to organizational culture in universities and the speed of integration and absorption of advances in science and technology that strongly impact entrepreneurial spirit[16]. The spin-off CEO's personal practical experience at university also influences the spin-off's organizational and human resource management nature. Spin-off CEOs tend to face different combinations of missing internationalization skills, some of which are related to personal characteristics[18]. Spin-off CEOs who are good at negotiating need unlimited patience, hide without lying, and inspire trust while recognizing that they cannot always trust. Others must be assertive, humble, and charming without being seductive. Such thinking is necessary to convince venture capitalists or other investors in the internationalization steps of the spin-off and to convince overseas sellers [15].

➤ *Ability to Transfer Technology to Create Products for the Market*

Spin-offs are considered direct technology transfers rather than patenting or licensing. The types of spin-offs vary widely; however, it is assumed that spin-offs from universities have high levels of technology transfer as faculty and graduate students move from parent institutions to subsidiary companies (spin-offs)[19]. Technology transfer typically involves (i) the source of the technology possessing specialized technical skills and (ii) transferring the technology to recipients who do not possess these specialized skills and who cannot create their own technology. Technology transferred to spin-offs from universities or corporations at startups can be considered their main asset. Therefore, factors related to available technological knowledge are believed to impact the likelihood of success of spin-offs after establishment. Spin-offs contribute to technology transfer in two stages: first, they transfer technology from the parent organization to themselves; second, they transfer technology to customers. Spin-offs from universities often develop in high-tech industries, such as biotechnology, medical technology, and information

technology, and their main activities involve technology and knowledge transfer from university to industry[8].

Studies in the pharmaceutical sector define "technology" as "a dynamic set of techniques, methods, skills and processes used in producing goods or services or to achieve the desired consumer benefits". This definition suggests that fourth-wave technology can (i) help pharmacists do better at what they currently do, (ii) expand the range of outcomes the profession can produce, (iii) combine both. However, technology is not only a cultural product but also a product that creates culture. This needs to be taken into account as we try to grasp the implications of technology as part of the future in pharmacy. Adopting technology can support the pharmaceutical industry as a valid player in the healthcare sector[20].

In terms of product innovation, some spin-offs aim to commercialize advanced technology and invest heavily in developing and introducing this technology to the market. These types of spin-offs may be the first companies to enter the market (first mover strategy). Through investing in highly novel technologies or products, they can benefit from having superior resources and capabilities, especially a unique position in the market, but they may also be subject to too high a risk[12]. Pharmaceutical manufacturing problems have the potential to significantly impact patient health care because violations of quality requirements can lead to product recalls and patient injuries. Furthermore, product defects, facilities, raw materials, and manufacturing issues are important factors that lead to risks when spin-off commercialized products enter the pharmaceutical supply chain[21].

B. *Spin-Off from University and Pharmaceutical Industry 4.0*

➤ *Market of the Pharmaceutical Industry*

Harnessing the emerging technologies of Pharmaceutical Industry 4.0 facilitates sustainable value creation, leading to a more flexible, intelligent, and personalized pharmaceutical industry, and thus, in the long run, pharmaceutical companies gain a competitive advantage. There is a need to implement a more sustainable pharmaceutical supply chain to accommodate future operations and manage pharmaceutical products throughout the entire life cycle [16]. In response, the entire pharmaceutical industry needs to consider how fourth-wave technology will affect the future of its clinical and commercial activities[20]. Society's behavior in purchasing consumer goods has changed over the past century thanks to new opportunities such as online stores and same-day delivery. These convenient ways of buying products also impact the pharmaceutical supply chain as things change from traditional wholesale and pharmacy structures to online store-based offerings[22].

To keep up with these challenges and view them as opportunities, the pharmaceutical industry needs to deploy a smart and sustainable pharmaceutical supply chain with a comprehensive view of product lifecycle perspectives. The

decentralization of pharmaceutical manufacturing directly affects the pharmaceutical supply chain by changing processes and distribution networks, adding new levels of complexity. On the other hand, it also creates new possibilities for solving current problems and meeting future needs. Spin-offs must understand how to approach smart and sustainable pharmaceutical supply chain across the entire lifecycle of pharmaceutical products in line with future developments in the pharmaceutical industry[22].

➤ *Spin-off in the Context of Technological Innovation in the Pharmaceutical Industry*

Emerging technologies have brought about dramatic changes in the field of pharmaceutical development as well as in manufacturing strategies. Pharma 4.0 is a pharmaceutical sector revolution involving automation and integration of the complete supply chain within an industry[21]. Pharmaceutical manufacturers and other participants in the pharmaceutical supply chain, including distributors, healthcare providers, pharmacies, etc., should also upgrade their services and technology. to meet the needs of future Pharma 4.0, including technologies from smarter logistics to especially personalized drug therapy[16]. From related techniques, spin-off researches and develops products that provide a viable solution suitable for society, e.g., automated ID cards, smart vehicles, patient-centered information exchange, cloud computing, big data analytics, drug order evaluation case studies as services, artificial intelligence (AI) enabled applications, and tools are targeted the most, followed by medical product distribution, pharmaceutical interviews, therapy education, and other services[23].

Therefore, effective use of advanced technologies is needed to replace manual processes with the automation of medication administration processes, including drug preparation and dispensing in hospitals or communities. This promising new challenge will enable efficient allocation of the pharmacy workforce in a resource-limited context by developing clinical decision support software for pharmacists that prioritizes patient prescription review for high-risk individuals or creates innovative tools[23]. Studies suggest that product and service innovation can bring competitiveness to spin-offs; however, the development process comes with many uncertainties and a high possibility of failure. This makes product/service innovation one of the riskier activities for a spin-off. Other studies show that funding, resources, and identified target markets are considered critical success factors of the products and services that spin-offs create[24].

University spin-offs can potentially become important factors in driving innovation-based economic growth at the regional level. However, it is necessary to carry out tripartite cooperation between universities and businesses and governance in this field[3]. The more famous a university is, the more research funding it can attract from various sources and the greater the potential for applying technological innovation[25]. Scholars often emphasize the importance of knowledge creation and dissemination at universities as an important driver of technological innovation and economic

growth, building an innovation ecosystem[26]. The ecosystem becomes especially important when it enables the creation of higher value than a single entity can create. The pillars of the innovation ecosystem are market access, human capital, access to internal or external financial sources, a favorable administrative system, and an appropriate cultural environment[3].

➤ *The Potentials of the Pharmaceutical Industry 4.0*

The healthcare industry is constantly evolving and trying to embrace the latest forms of technology to optimize functionality within the healthcare system. Pharmaceutical service innovation is considered a valuable addition to the pharmaceutical supply chain. It is a clear strategic direction guiding the pharmaceutical industry development's overall strategic flexibility. Information technology is also used as a key element of service delivery. This is only successful when the pharmacy owner is committed to providing services and seeks to improve the quality of pharmacy services[27].

Management weakness that can undermine the public image of the pharmaceutical industry is having the greatest social impact on the profession. Pharmacists should return to their fundamental relationship with society by accepting moral responsibility for controlling the safe, appropriate, and effective use of drugs. Pharmacies in the pharmaceutical supply chain need to undergo a process of professional reconstruction and self-renewal to become providers of new models of social practice. For example, pharmacies have traditionally based their operational processes for dispensing and care of pharmaceuticals on the assumption that patients will interact directly with pharmacists. Fourth-wave technology will advance communication and connectivity in countless ways that connect billions of people to the internet. For example, Big Data and AI can identify patient needs, track medication use, and look for pharmaceutical problems[20].

Leading pharmacists are aware that technology can disrupt society and the economics of pharmacy[20]. There is a growing need for personalized medicine in an aging population with increasingly complex dosing regimens (related to the number of medications per day for patients with multiple medical conditions, daily dosing times, and multiple dosage forms). Complicated or complicated, special instructions for use...). In addition, the clinical pharmacist is uniquely positioned to address all aspects of the quadruple goals: improving access to health, reducing costs, improving clinical outcomes, and optimizing healthcare team satisfaction. Therefore, using advanced technologies to support clinical pharmacists is necessary. This has begun over the past decade with the automation of the medication dispensing process, including drug preparation and dispensing at the pharmacy. Hospitals or communities should replace manual processes[23]. The future pharmaceutical industry needs an innovative and sustainable pharmaceutical supply chain throughout the entire lifecycle of pharmaceutical products supported by advanced technologies[16].

III. METHODOLOGY

This study applies one of the functions of systematic literature review to build a selection framework: articles, research works, books and projects at Nguyen Tat Thanh University, the internet, and other related documents[28]. The filter support available in that database and searching for keywords on the internet, 36 documents were selected to support the article content [29]. A thorough reading of the chosen documents was narrowed down to three categories for a spin-off from the university in the innovation ecosystem, supporting human resource development and context—the landscape of pharmaceutical industry 4.0. The data source is previous empirical studies on startup and spin-off development cases. We took The following steps to achieve this study's goals [30]: (i)First, we collected relevant articles from research databases: Google Scholar, Scopus, ScienceDirect, and Web of Science. Article collection is done by applying a set of keywords related to the study's content; (ii)Second, track and conceptualize spin-offs from the university in the innovation ecosystem and pharmaceutical industry 4.0. These results are the conceptual basis for analyzing and correlating the selected articles; (iii)Third, examine and outline the important characteristics spin-off from the university related to the pharmaceutical industry. In this step, irrelevant articles are removed and new supporting articles are added; (iv)Fourth, develop a spin-off model from the University in the innovation ecosystem related to the pharmaceutical industry; (v) Fifth, imply the

main characteristics of concern. A spin-off from the university is a solution to support the implementation of the pharmaceutical industry development strategy in Vietnam in the future[30].

This research approach will facilitate the development of a comprehensive framework that identifies spin-off sustainability issues in the pharmacy sector at the university. In addition, the results of the analysis also provide information related to future research that should be conducted[30].

IV. FINDING OF THE STUDY

Spin-offs are small and medium-sized startups with little investment capital (of course depending on the specific field) and can easily adapt to market changes. Some studies have shown that the characteristics of this business model are mainly reflected in the association with intellectual property units (research centers, universities). Accordingly, these businesses are formed from research organizations (institutes, schools) and have not really separated from the parent organization to operate independently and autonomously. Many studies consider the establishment of spin-offs from universities as an important resource for regional and national economic growth[3, 19]. Table 1, Based on selected literature reviews, the study examines the important points that determine the formation of university spin-offs and should become the basis for their application.

Table 1: Implementation Characteristics Spin-Off in the Pharmaceutical Industry

Point of Views	Function application	Source
Spin-offs from universities support human resource development	The foundation for forming the Spin-off Spin-off resources Spin-off strategy Constructive policies and support from the government	Nguyen (2022); Steffensen (2000); Randriamaromila (2019); Fici (2016); Toan (2019); Soetanto (2011); Ielasi (2024); Bagchi-Sen (2022)
Spin-offs from universities support human resource development	Participate in entrepreneurship education Develop an entrepreneurial spirit Ability to transfer technology to create products for the market	Steffensen (2000); Toan (2019); Soetanto (2011); Van Geenhuizen (2015); Ding (2018); Bajis (2018); Buenstorf (2009); Jung (2018); Baines (2020); Mali (2022)
Spin-off from university and pharmaceutical industry 4.0	Market of the pharmaceutical industry Spin-off in the context of technological innovation in the pharmaceutical industry The potentials of the pharmaceutical industry 4.0	Ding (2018); Baines (2020); Wölfle (2022); Pachciarek (2023); Mali (2022); Baines (2019); Smith (2008); Bigliardi (2013); Quan (2021); Ding (2018); Ranchon (2023)

A spin-off from the university will be developed with components in the proposed startup ecosystem, as shown in Figure 1. The spin-off must be linked with strong support from constructive government policies and laws, the increasingly perfect laws of the pharmaceutical industry[11, 31]. In addition, spin-offs must identify the opportunities and challenges when participating in the innovation ecosystem in the startup education environment and the potential of the pharmaceutical industry serving food and implementing the national pharmaceutical industry development strategy.

V. DISCUSSION

A. Policies to Create and Support Developing Spin-Offs from Universities in Vietnam

To promote spin-off development from universities, government institutions, and policies need to synchronize the public and private sectors involved in creating and supporting organizations. For example, it is necessary to promote policies on technology transfer, patent registration, coordination mechanisms between relevant parties, suitable practice mechanisms for public-private cooperation... and many policies related to the formation of public-private partnerships. And support the activities of spin-offs that belong to universities or are formed thanks to scientific research achievements from universities[11].

The Government's role in establishing an institution and policy system to ensure long-term resources is, first of all, promoting business and university linkages, then promoting dynamism and a development environment. Developing commercial and entrepreneurial activities in universities is extremely important. In addition, universities' specific policies on resource allocation (finance, mechanisms, and human resource policies) will be the decisive push and lever[11]. The Government issued Decree No. 109/2022/ND-CP dated December 30, 2022, regulating the organization and management of science and technology activities in higher education institutions. To promote investment in developing scientific and technological potential in universities, innovation centers, small and medium-sized business incubation facilities, and technical facilities must be formed to support small and medium-sized businesses. This co-working area supports small and medium-sized enterprises to start creative startups in the university's innovative startup ecosystem.

Decree No. 109/2022/ND-CP clearly states that the responsibility of the Ministry of Education and Training is to guide the proposal, formation, and development of innovation and startup support centers in educational institutions university; Develop a network of experts, advisors, and consultants for creative startups, connecting with the national innovative startup network; Guide higher education institutions to exploit available infrastructure, equipment, laboratories, testing, and space of higher education institutions to serve the operations of startup support centers innovation industry. In addition, Decree 109/2022/ND-CP also determines that the Ministry of Science and Technology is responsible for guiding the autonomy mechanism for science and technology organizations in higher education institutions, developing and implementing a pilot project to support the establishment of science and technology enterprises to exploit, perfect and commercialize intellectual property rights in higher

education institutions; Guide higher education institutions to establish small and medium-sized business incubators, technical facilities to support small and medium-sized enterprises, and co-working areas to support small and medium-sized businesses with innovative startups.

Studies show that experiences in other countries demonstrate the important role of the government in providing financial support and direct interventions to promote spin-off development activities from universities. National governments initially have budgets to fund scientific research, then gradually decrease and shift to promotion among relevant parties. In particular, special priority is given to technology transfer projects for commercial purposes, and scientists are encouraged to open spin-offs to promote the quick transfer of scientific research results to the business sector and efficiency. This reduces the budget burden for scientific research and universities, and more importantly, it motivates scientific research and innovation activities in the academic world to help them pay attention. To the result of serving society and sustainable business operations of businesses[11].

In pharmaceuticals, the government approved Decision No. 1165/QĐ-TTg dated October 9, 2023, the national strategy for developing the pharmaceutical industry to 2030 with a vision to 2045 in Vietnam. With this decision, the government is interested in continuing to complete the institutions and laws of the pharmaceutical sector: (a) Completing the pharmaceutical legal system, including policies to encourage investment with high incentives, especially for research and technology transfer activities; (b) Complete regulations on protection and enforcement of intellectual property rights for drugs in Vietnam; (c) Have policies to encourage investment in establishing and developing internationally recognized clinical testing centers in new drug development.

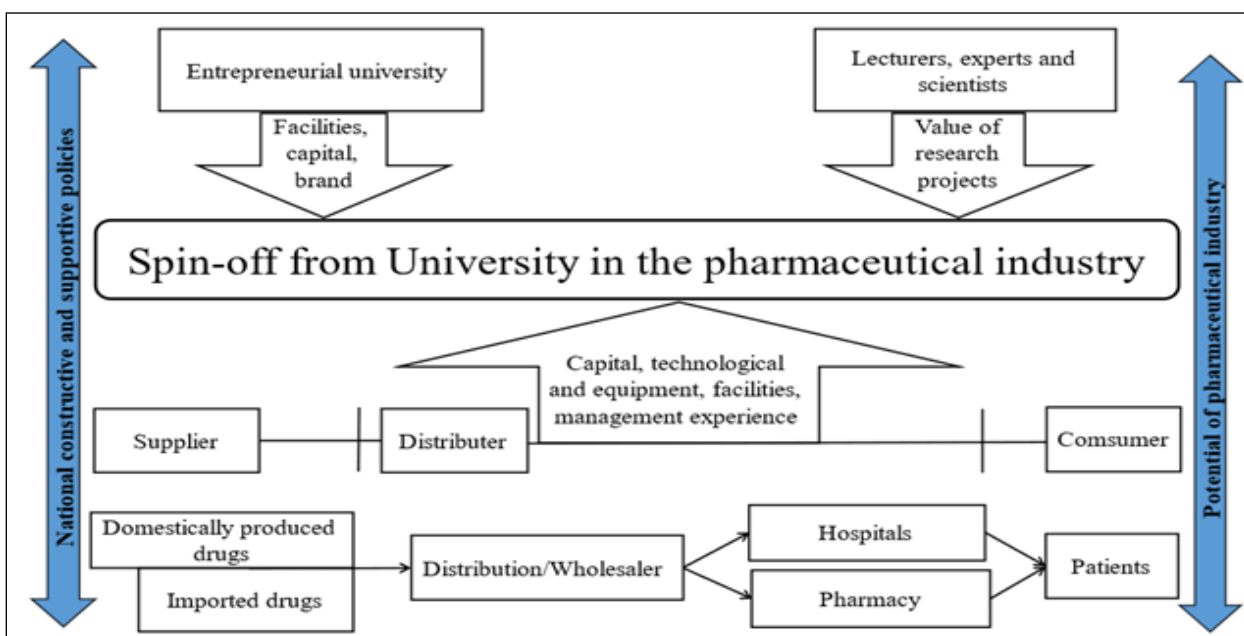


Fig. 1. A Framework of Spin-Off from University in the Pharmaceutical Industry

B. Opportunities and challenges spin-off from university in the field of pharmacy in Vietnam

➤ Spin-Off Opportunities

The role of universities has expanded, including increased collaboration with industry. For so-called entrepreneurial universities, there is an emphasis on academic knowledge that can be used more effectively as a source of creativity and innovation in the industry[1]. Collaboration between different organizations is critical to creating a sustainable pharmaceutical supply chain. Collaboration between pharmaceutical companies and spin-offs has strategic significance with opportunities for spin-offs to sustainably expand research and development activities, commercialize, and participate in the pharmaceutical supply chain:

First, Vietnam is currently home to more than 100 million people, becoming the 15th most populous country in the world. The emergence of the COVID-19 pandemic has spurred significant advances in biotechnology and vaccines and shortened drug and vaccine approval times globally. Vietnam's healthcare system has significantly progressed in developing medical products, vaccines, and technology. This poses logistical challenges to improving access to essential medicines at reduced healthcare costs[4]. The value of the global pharmaceutical industry has grown significantly over the past decade with increasing demand for product effectiveness. However, problems such as drug shortages, inaccessible counterfeits, antibiotic resistance and rise in pharmaceutical fraud its vulnerability. The Covid-19 pandemic has also exacerbated the fragility of pharmaceutical supply chains. In such environments, developing a resilient pharmaceutical supply chain is imperative[32, 33].

In Vietnam's pharmaceutical supply chain, pharmacies often provide drugs, beauty products, and functional foods. Product diversity needs to aim at satisfying the needs of different customers. The level of service provided can range from self-service (front of the store) to authentic, personalized service throughout the store. Customers expect not only medicines but also a wide variety of products available at the pharmacy so that they can buy everything they need and save time by not having to look for the necessary items. Combining products that suit the needs of many customer groups will become a success factor for customer satisfaction[34]. Decision No. 1165/QD-TTg of the government's pharmaceutical industry development strategy requires ensuring a proactive and timely supply of quality, safe, effective drugs at reasonable costs for disease prevention needs medical treatment, overcoming the consequences of natural disasters, disasters, public health incidents and other urgent needs for medicine, meeting the requirements of socioeconomic development, ensuring national defense and security.

Second, Vietnam aims to build a solid healthcare infrastructure from the grassroots up. District health centers and commune health stations are called "basic health care systems" (providing basic health services). Even though

strides have been made to improve health outcomes, the healthcare system still faces increasing challenges to keep up with the country's population growth[4]. The Vietnamese government is still unable to support elderly care in the community adequately. Most responsibility for caring for older people is assigned to the household economy and family members. According to current trends, Vietnam is expected to face the problem of an increasing elderly population, just like in developed countries. Therefore, the government needs to explore elderly care models and exploit the potential of older people to contribute to society instead of increasing the dependency ratio[2]. Decision No. 1165/QD-TTg of the Government's pharmaceutical industry development strategy mentions ensuring the rational, safe, and effective use of drugs through a system of synchronous measures, which focuses on promoting, improving capacity and efficiency of clinical pharmacy activities, pharmacovigilance, and building a digital pharmacy data ecosystem.

Third, Vietnam also has to face public health emergencies in the future because there may be a gap between the supply and demand of drugs, vaccines, biological products (for example, test kits or probes), and other medical supplies. The pharmaceutical industry is rapidly growing in capacity to meet growing demand. The opportunity for spin-offs from universities to participate in the pharmaceutical supply chain supports recognized pharmaceutical and biotechnology establishments to accelerate domestic research and development activities and contribute to solving some of these logistical barriers while optimizing cost efficiency[4].

Many studies have recommended improving the Vietnamese pharmaceutical industry's ability to participate in globalization. Domestic pharmaceutical companies focus on investing in producing new drugs and improving drug quality, gradually leaving the generic drug market segment and producing quality specialty drugs for the broader market rather than export. Companies that need to develop need to develop supporting industries for the pharmaceutical industry, producing raw materials and input materials of the pharmaceutical supply chain, helping to narrow the price gap between exported Vietnamese drugs and other countries. The domestic market needs to be more open to foreign investors, especially manufacturers wishing to set up factories in Vietnam[5].

Decision No. 1165/QD-TTg of the government's pharmaceutical industry development strategy mentions specific science and technology goals: (a) Promote research and participate in international coordination to develop brand-name drugs, generic drugs, specialized drugs, generic drugs with high-tech dosage forms, vaccines, reference biological products, similar biological products, drugs from medicinal materials and application of modern drug preparation technology; clinical trial research, bioequivalence assessment; (b) organize the implementation of pharmaceutical science and technology tasks, focusing on contents related to the development of the pharmaceutical industry and pharmaceutical chemistry industry; (d) focus on

investing in research and application of advanced and modern technology in preserving endemic, precious and high economic value medicinal gene sources, and researching and creating new varieties from medicinal gene sources in the future. water and imported planting techniques for high yield and quality; in preliminary processing, extraction, preparation and standardization of medicinal herbs and drugs from medicinal herbs. Collect, research, and inherit medicinal recipes and experience using medicinal plants of ethnic groups in the community.

➤ *Spin-Off Challenges*

The university spin-off model is encouraged by current policy but is extremely difficult to manage and implement[1]. With its policy for the development strategy of Vietnam's pharmaceutical industry, the Vietnamese government is a spearhead industry, gradually moving towards modernity, Developing the pharmaceutical industry, pharmaceutical chemistry industry, domestically produced medicinal materials, increasing export value, and deeply integrating into the global pharmaceutical supply chain. Spin-offs want to participate in the pharmaceutical supply chain, identifying challenges:

First, Revolution 4.0 will place increasingly new requirements on workers. The education sector needs to make appropriate adjustments to meet new human resource requirements in addition to labor and employment policies[35]. Studies show experiences from countries in the process of developing spin-off. Universities always start from a period of change by linking training programs, scientific research activities, and community service activities with requests from stakeholders, especially the governments, industries, and businesses, because they are not only departments that use human resources, knowledge, and technology but are also investment partners and jointly operate activities that create added value in the supply chain of their respective fields[11].

In Vietnam, the pharmaceutical industry development strategy is for 2030 with a vision for 2045, according to Decision No. 1165/QĐ-TTg. Vietnam has a specific orientation and roadmap to standardize the pharmaceutical workforce's basic training, continuous training, and advanced training activities. Improve the quality of pharmaceutical human resource training, prioritizing the fields of clinical pharmacy, quality management, research and development, processing, and drug technology transfer to meet the needs of social development and national integration. The pharmacist training program enhances specialized training on vaccine and biological product production, bioequivalence research, clinical testing, processing, and technology transfer.

Second, the fact that universities have a large (or even dominant) ownership ratio will reduce the appeal of the spin-off to outside investors who "fuel" the spin-off machine of my work. In addition, owning a large stake means the university can strongly dominate spin-off activities, while the quality of corporate management personnel is not the university's strength. Therefore, the world's reality shows that the success rate of spin-offs will decrease the greater the

university's ownership ratio. Besides the lack of investment resources, the lack of a startup mechanism to balance the economic interests of scientists and management agencies is also why establishing and developing spin-offs from universities isn't easy [2].

In Vietnam, the government has Decree No. 109/2022/ND-CP dated December 30, 2022, regulating university science and technology activities. Public universities can contribute capital with intellectual property that results from scientific and technological tasks originating from the state budget assigned by competent authorities to manage and use for joint ventures and partnerships if necessary. Meet the conditions prescribed by the law on science and technology, the law on management and use of public assets, the law on intellectual property, the law on enterprises, and other relevant laws. Public universities are assigned the right to use assets in the form of increasing assets. Private universities are assigned ownership rights to assets and must return the value of assets due to scientific and public tasks. Technology is formed from scientific and technological tasks originating from the state budget following the law on intellectual property and the law on management and use of public assets. The commercialization and registration of science and technology enterprise certification is carried out following the provisions of law.

Third, universities in this new context must transform their management organization model and operating methods with operational efficiency and responsiveness of stakeholders as the goals. Such organization and operation are also known as the enterprise university model (Entrepreneurial University). This does not contradict the trend of innovating and perfecting university administration. On the contrary, it has the effect of promoting and strengthening the process of commercialization and market service orientation in university activities, helping develop production and business disciplines[11].

Decree No. 109/2022/ND-CP also stipulates that universities can establish enterprises according to the law on enterprises, following the development orientation of higher education institutions. Enterprises from universities that meet the conditions according to regulations can register for science and technology enterprise certification. Science, technology, and innovation activities from the university mentioned include intellectual property activities; scientific research activities of lecturers and learners; technology transfer activities; cooperation in science and technology between universities and businesses outside universities; startup and innovation ecosystem; international cooperation in science and technology; academic integrity; scientific and technological information activities.

VI. CONCLUSIONS

The central message of this article is that university spin-offs are necessary and have an important role in the market, especially in the pharmaceutical sector. They carry out continuous innovation, allowing the continued application of useful personal innovation knowledge and

skills acquired during university work. Therefore, necessary spin-offs from universities can be the right means to break organizational inertia and bring new ideas to the pharmaceutical market in Vietnam. Universities and research institutes will form certain research products through scientific research and technological development activities. One of the output products of scientific research is new technologies that can be applied to life, bringing economic benefits to both societies and researchers. Spin-offs in the healthcare sector, especially the pharmaceutical industry, are innovative companies integrated into the university system innovation process, aiming to manage academic startup services to continue displaying research results through the implementation of business activities. Spin-offs from universities are a tool to promote knowledge transfer and technology transfer to the commercial sector and pharmaceutical manufacturing. They constitute an important level of competition, capable of driving the development of the pharmaceutical industry by making better-understood university-researched technological solutions that contribute to sustainable development and improving the performance of the pharmaceutical supply chain in the pharmaceutical industry development strategy in Vietnam[36].

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