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Health care solidarity versus health care industry

What can we learn from the coronavirus crisis?

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Before the coronavirus crisis hit, newspapers were filled with headlines concerning the rising costs in healthcare and how they might be contained efficiently. The justification of innovative therapies costing millions must be discussed. The coronavirus pandemic has put health care at the centre of media attention and highlights how important a well-functioning health system is – and that it comes at a cost.

Looking for a "new normal" amidst the coronavirus pandemic, it is more than appropriate to rethink costs in the health care system. The question is whether it is ethically justifiable to make billions in profits at the expense of ill people. Our health is one of the greatest goods we have, and many are willing to spend a lot of money on it. The global health care sector is expanding rapidly and has proven to be extremely lucrative, with the highest profit margins in the economy.

Health service versus health industry

In his book *Business Health - How the Market Abolishes* the Art of Healing, medical ethicist Giovanni Maio describes the consequences of the economisation of health care: "The health care system is part of the social system of our society. Part of our wealth is invested in health care for the benefit of all. A health industry, on the other hand, is part of the economic system. Cap-

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ital owners invest in this health care industry and they expect a return, for the benefit of few. You can't have both at the same time, because the goals of these two systems fundamentally contradict each other". Nowadays, many corporations pursue profit maximisation, which is fundamentally incompatible with a health system based on solidarity.

The role of the pharma industry

Since the early 1980s, the global pharmaceutical market has grown steadily, reaching over 1000 billion US dollars a year. Half of the market exists in the United States. The top 10 pharmaceutical companies generate two thirds of the sales (www.pmlive.com). Since the Reagan presidency, the big pharmaceutical companies have followed the so-called "blockbuster model" (drugs with annual sales of over 1 billion dollars) with profit maximisation within, but also outside of legal boundaries, with profit margins often exceeding 20% [1, 2]. In 2003, Pharmaceutical profit surpassed the cumulative profit of all Forbes-listed industries. However, the golden days of the "blockbuster model" are coming to an end, now there are numerous generic drugs on the market for many common diseases such as hypertension, asthma, depression and tumours. In addition, the patent protection of many "box office hits" is expiring, and generic drugs have become significantly cheaper. Now, "personalised medicine" is emerging as the new buzzword in pharmaceuticals [1]. The development of so-called orphan drugs, i.e. drugs for rare diseases such as cystic fibrosis, spinal muscular atrophy and tumours, has opened up a promising future market for the pharmaceutical industry. Legal incentives such as the extension of patent protection have made research into orphan drugs attractive, which has led to astronomical sums being charged for such drugs today.

Compensation for high development costs?

Representatives of the pharmaceutical industry justify high prices of drugs with high development costs. However, many discoveries and innovations are made in research institutions at universities, which are financed with public money. This often results in small start-ups being bought up by large corporations for horrific sums, which are then booked as development costs. The mean development costs for a new drug have been the subject of controversy for years; so far the most cited studies by Di Masi et al. estimated these costs (assuming 11% loan costs and a clinical success rate of 12%) at \$1.1–2.8 billion [3]. A recent study examining 355 new FDA-approved drugs in 2009-2018 arrived at a signifi-

Which role do patents play?

Patents are neither bad nor good. They can contribute to the benefit, but also to the detriment of a society and its economy. They only make sense if the overall benefit for the general public predominates. Only then can it be politically justified that the state grants a monopoly to individuals or companies, which can turn it into a non-competitive business. Today, patents are often misused to maximize profits without any corresponding benefit. Patent disputes also prevent innovation and delay or even hinder the development and market launch of generics and biosimilars. Why patents in oncology are harmful today or "It's the economy, stupid!" Swiss Cancer Bulletin 2020; 202: 114-7

cantly lower cost estimate: After considering the cost of failed trials, the median cost of research and development investment to bring a new drug to market was calculated to be \$ 985 million (95% CI: \$ 684-1229 million) [4]. Today, pharmaceutical companies are investing far more in marketing, manufacturing, and sales than in research and development [5]. In the past 20 years, the pharmaceutical and healthcare product industries spent \$ 230 million annually on lobbying in the United States alone, more than any other industry [6]. The massive purchase prices for "pipeline shopping" are also included in the drug development costs. It is therefore not surprising that the companies are hardly interested in taking care of a high-quality generic or biosimilar market. The number of essential generic drugs that are no longer available is growing every day, and basic supplies for our population is increasingly at risk.

Who determines the price of a new drug?

Many do not know how the pricing of a new drug works and that in the USA the pricing is in no way regulated it is left to the companies. Therefore, all pharmaceutical companies are trying to get approval for their new drugs in the USA, since the American healthcare market is the most lucrative in the world and generates the most profits. After approval by the American health authority FDA, the company sets the price for the drug as it sees fit. As stock corporations, the companies are committed to "shareholder value", which serves to generate maximum profit, and not to the patients or the common good of our society. Once the maximum price has been set, it will be further protected by many regulations and patents. As a result, the drug is withdrawn from free trade and its price kept high long term [2]. In Europe, despite HTA processes, most authorities align themselves with the American price structure. It is not surprising, then, that the pharmaceutical industry is one of the most profitable industries.

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In Switzerland, there have been patents for the chemical sector since 1907, but it was not until the "Bayh-Dole Act 1980" that public research institutions were allowed to patent and license their findings, to found and sell start-ups on attractive terms [7]. As a result, US companies were able to be more innovative, to become more productive and to keep profits in the US. Surprisingly, it has not yet been proven that patents serve to promote new inventions, let alone that they are indispensable for an innovation process [8].

In summary, the profit margin of the pharmaceutical industry is far too high compared to other branches and no longer reflects the investment risk of development costs. Most of the claimed costs of innovative drugs today reflect the purchase of start-ups as well as lobbying and PR activities, not the real development costs. There is an urgent need for complete transpar-

ency in pricing with comprehensible pricing models and - where necessary - compulsory licenses and bans on excessive marketing measures for the launch of expensive drugs. It requires a political will to establish internationally valid, fair rules. "Business as usual" is no longer tenable even in the richest economies, especially since the Corona crisis hit. A health care system based on solidarity must not turn into such a one-sided profit-maximizing health care market, where large corporations can excessively enrich themselves at the expense of ill people.

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The essentials in brief

- The global pharmaceutical market has grown steadily since the early 1980s. Pharmaceutical profit exceeded the cumulative profit of all Forbes-listed industries in 2003.
- The number of essential generics that can no longer be supplied is increasing daily, the basic supply of our population is increasingly at risk.
- As a stock corporation, pharmaceutical companies are committed to "shareholder value" and not to patients or the common good of our society.
- The health care system which is based on solidarity must no longer degenerate into a health market that is one-sidedly geared to profit maximization.