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Medical research without patents: It's preferable, it's profitable, and it's practicable

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ABSTRACT

This article addresses the question of the possibility of medical research without patents, a major issue in healthcare research and policy. We discuss and evaluate the relevant scientific, economic, societal, and moral aspects of our system of funding and organizing the research, development, manufacture and sale of prescription drugs. The focus is on the patent practices of big pharmaceutical companies. We analyze and critically assess the main features and impacts of these practices. In a positive sense, we propose an approach to organizing and funding drug research that prioritizes its public interest rather than its privatization through patenting. For these purposes, we first demonstrate that producing prescription drugs through patenting has serious drawbacks. Second, we develop a concrete alternative (medical research without patents) that is shown to be scientifically, socially and morally preferable, economically and financially profitable, and socio-politically and organizationally practicable.

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The question of the possibility of medical research without patents constitutes a major challenge for research policy. In this article, we discuss and assess the relevant scientific, economic, societal, and moral aspects of our system of funding and organizing medical research. The focus is on the patent practices of big pharmaceutical companies. We analyze and critically assess the main features and impacts of these practices. In a positive sense, we propose an approach to organizing and funding drug research that prioritizes its public interest rather than its privatization through patenting.

The following four facts demonstrate the urgency of constructing a substantially different system of drug production and, at the same time, which direction such a change should take. First, there is the unsustainable growth of the costs of prescription medicines. Second, high drug prices

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provide an enormous incentive for continuing corruption and abuses in the form of misrepresenting the safety and effectiveness of drugs and encouraging their use in situations where they may not be appropriate. Third, the current system is one in which the (mostly big) pharmaceutical industries make excessive profits (much larger than what is usual in other commercial businesses), while they pay hardly any tax on their profits. Fourth, a substantial part of the entire system of drug production is paid by public tax money, through various contributions of national governments and governmental institutions. The latter fact, however, does not have a mitigating effect on the excessive drug prices the public has to pay in their hospitals and pharmacies. The result is that the public pays twice for its medicines: first, via its significant financial contributions to the various stages of the drug production system; and, second, for generally overpriced and often excessively expensive medicines.

Our conclusion is that these facts require and justify a shift in our policies for drug production: from privatization through patents to medical research in the public interest.[1] In the first section we demonstrate that abolishing medical patents is scientifically, socially and morally preferable. The second section argues that it is also economically and financially profitable. In the final section we introduce and explain a concrete model of how to do medical research without patents in a way that is socio-politically and organizationally practicable. Along the way, we emphasize the importance of a broad approach to the relevant issues. That is, any approach should take into account the stages of research, development, manufacture, marketing and sale of drugs (for brevity's sake, we refer to the collection of these stages as the "production" of drugs).

In this article, our primary focus is on medical research in wealthier countries. But of course, the far greater affordability of generic prescription drugs in a system without patents will also be to the advantage of low and middle-income countries. After all, it is the people of these countries who suffer most from the current monopolistic system.

Furthermore, patents on the results of medical research are not limited to drugs. They may include diagnostic and therapeutic processes and devices. In this article, our claims are limited to drug patents. But a more comprehensive analysis and assessment should also address the broader subject of patented medical processes and devices.

Finally, a terminological point about "prescription drugs," a term used for drugs approved and prescribed by medical authorities. A closely related notion is "essential medicines." This includes those drugs that are rightly seen as essential (for instance, some expensive "orphan drugs" for children), but that are, for some reasons and in some contexts, not prescribed; and it excludes some drugs (for instance, novel "me-too drugs," which hardly add any clinical value to existing ones) that in fact are, but should not be,

prescribed. For reasons of convenience, we use the term "prescription drugs," but are aware that some of those drugs might be subject to dispute.

1. Medical research without patents: It's preferable

In this section, we argue that abolishing patents on the results of medical research is not only possible but also preferable. In debates on this issue, it is often declared to be an undeniable fact that medical research without patents is simply impossible. Generally speaking, the actual manufacture of drugs is *much* cheaper than the research and development (R&D) required to get a drug approved and registered. Therefore, the pharmaceutical industry claims it needs a period of patent protection, usually 20 years, that first, gives them the opportunity to test their drugs and have them approved; and second, grants them an *exclusive* legal right to sell the approved drugs (or to license others to sell them). The basic claim, then, is that only this patent system allows the pharmaceutical industry to recover its high R&D investments. In this sense, David Resnik writes:

> If companies could no longer patent products, they would greatly decrease their R&D investments, which would lead to a drastic reduction in the funding for scientific research. Since governments do not have the money that would be needed to compensate for this reduction in private funding, it is likely that scientific research—and the public interest—would suffer greatly. (Resnik 2020, 173)

Thus stated, this argument applies to all product patents, but it is also frequently used with respect to the patenting of drugs as the products of medical research.[2]

The aim of our article is to refute this argument. Briefly stated, our refutation consists of two steps. The first addresses the first sentence of the above quotation. We show that the excessive profits (resulting from highly overpriced drugs) made by the pharmaceutical industries and their shareholders are made possible by substantial public investments. In the second step we argue that the money that will be saved in a system with normal rather than excessive profits can be employed to establish a publicly funded and regulated R&D system for drugs (and possibly for other results of medical research). Thus, our second step explicitly questions the second claim of the above quotation.

In an abstract way, the claim that drug research without patents is economically impossible is clearly false. The reason is that, apparently, there is a huge amount of money available that is being paid for our current drugs by governments, insurance companies and individual patients. In principle, this same amount could be spent on the basis of a different system,

a system without patents. Of course, in practice the abstract possibility of creating a new public system is not enough. In addition, we have to demonstrate that medical research without patents is scientifically, socially and morally preferable, that it is economically and financially profitable, and that it is socio-politically and organizationally practicable.

This section argues for the scientific, social and moral preferability of such a policy change. For this purpose, we provide a concise review of the problems of the current system of drug research, which is strongly dependent on the interests of private, and usually big, multinational pharmaceutical companies. Our review is based on a large body of academic literature that analyzes and critically assesses the role of these pharmaceutical companies.

For a start, there are the many general criticisms of the commercialization of medical research. In addition to patenting practices, they address a whole range of dubious aspects of this commercialization. In particular, these studies analyze and assess many cases of the epistemic and moral corruption that occurs as a consequence of conflicts between epistemic and moral standards, on the one hand, and the economic and financial interests and power of the big pharmaceutical companies, on the other.[3]

In a recent article, Bennett Holman advocates a balanced overall view of the relations between industry and academia, which takes into account both the more positive assessments by policy researchers and the more critical evaluations by philosophers of science. He is, however, unreservedly negative about the specific case of the past and current impact of pharmaceutical industries on medical research. In this case, "we have in-depth accounts of numerous drug disasters" (Holman 2021, 9). To illustrate, consider how Lisa Cosgrove and coauthors summarize the results of their study of the development of vortioxetine, a new anti-depressant.

> The economies of influence that may intentionally and unintentionally produce evidence-*biased*—rather than evidence-based – medicine are identified. This is not a simple story of author financial conflicts of interest, but rather a complex tale of ghost management of the entire process of bringing a drug to market. This case study shows how weak regulatory policies allow for design choices and reporting strategies that can make marginal products look novel, more effective, and safer than they are, and how the selective and imbalanced reporting of clinical trial data in medical journals results in the marketing of expensive "me-too" drugs with questionable risk/benefit profiles. (Cosgrove et al. 2016, 257)

This and many similar studies have been crucial in raising academic and public awareness of the questionable practices of the pharmaceutical industries.

However, in addition to these studies we need a more general analysis and assessment of our *entire* system of drug production, thus including the research, development, manufacture, marketing and sale of drugs. A common claim in support of patenting the results of medical research is

that it is the pharmaceutical companies that bear all, or almost all, of the risks and expenses of the system of drug production. Therefore, granting them a monopoly on the sales of approved drugs is seen to be justified. However, a more detailed account of what constitutes this entire system shows that a vast amount of public money is already being invested in this system. Because this fact is crucial for the purpose of increasing general awareness about the urgency of a substantial change in our healthcare policies, we provide a brief sketch of the stages of drug research, development, manufacture, marketing and sales.

First, there is the creation and maintenance of a public infrastructure of medical education and research. This is a stage that is usually overlooked in discussions and policies of drug pricing, perhaps for the reason that it is difficult to put an accurate price on having an appropriate infrastructure available. However that may be, the amount of invested public money must be huge (especially in the wealthy parts of the world). Hence these public contributions should not be overlooked, nor, as is usual in mainstream economics, should they be defined away as an "externality" that is irrelevant to the price of the produced goods.

Second, this infrastructure enables the actual performance of medical research at (public or nonprofit) universities and research institutes. It includes both basic and application-oriented research. A significant part of this public knowledge is used by pharmaceutical industries in the subsequent stages of the system of drug production. A common arrangement is that public medical researchers who have a promising idea about potential drugs enter into a contract with private companies. A basic element of this contract is the application for a patent that, if granted, will be held by the involved companies. Again, it is difficult to quantify accurately the total public expenses that have facilitated the medical research that is later privately exploited by commercial parties.[4] What we can conclude, however, is that during the past decades the public contributions to early-stage drug research have significantly increased as compared to the private contributions.

Consider the following two examples. Mark Robinson has provided a carefully documented study of the development of translational biomedical knowledge in the US between 2003 and 2014. He concludes that in the case of translational medicine (broadly, the research to turn basic science into clinical applications)

> the partnerships between universities and pharmaceutical companies must be understood as part of a larger strategy of R&D *externalization*, through which companies could outsource projects onto partners, enabling companies to retain a pipeline of R&D innovation without the costs and risk of executing these projects internally.[5]

To a significant extent, this externalization implied the transfer of translational research from the private to the public sector.

A similar conclusion is drawn by Irene Schipper, Esther de Haan and Roberta Cowan. Their detailed report focuses on drugs developed with Dutch public money. It provides a wealth of information about the public funding of biomedical R&D in the Netherlands, including a case study of the development of a drug for a type of lymphomic cancer. Their report shows that the strategy of large pharmaceutical companies has been shifting from "Research & Development" to "Search & Development." That is, these companies are "stepping away from playing a part in early drug development, preferring to leave this phase to universities and publicly funded research institutes." The conclusion is that these findings "contradict the pharmaceutical industry's mantra that it pays for all expensive clinical trials" (Schipper, de Haan, and Cowan 2019, 10).

This brings us to the third stage, the stage of testing the effectivity, safety and possible side effects of potentially useful drugs, usually by means of RCTs (randomized controlled/clinical trials). The estimates of these costs vary widely, in part due to lack of transparency on the side of the pharmaceutical companies. However that may be, what is clear is that these companies try to limit these costs, both with the help of a range of epistemically and morally unacceptable methods (see the literature mentioned in note 3) and by means of their strategy of passing on risks and expenses to the public sector.

Fourth, to have their drugs approved and registered for general use pharmaceutical companies need to submit the results of their tests to regulatory agencies. The task of these agencies (for instance, the Food and Drug Administration in the US and the European Medicines Agency in the EU) is to assess the (claimed) effectivity, safety and side effects of proposed drugs. Relevant for our article is that their decision procedures do not take into account the financial aspects of the new drugs and the question of what they add in terms of clinical value. These regulative organizations clearly serve the public interest in the availability of effective and safe drugs. Even if most of their budgets are covered by the fees of their users, the remaining public investments constitute a necessary condition for an appropriate system of selling drugs, which also serves the pharmaceutical industry.

The final stage concerns the manufacture, marketing and sale of approved drugs. As in the first stage, there is a substantial public contribution by means of an infrastructure that takes care of the education of physicians, pharmacists and their associated personnel. The general approval of a drug does not tell you when its prescription is appropriate for particular patients. Without the knowledge and skills of physicians and pharmacists (made possible by a publicly funded knowledge infrastructure) a working system of prescribing and selling effective and safe drugs is

unthinkable. As a matter of fact, drug producers (and their economic results) depend on such a "market infrastructure" to a much larger extent than most other manufacturers (for instance of soap or chocolate). Their extensive advertising, lobbying, pampering and bribing activities show that pharmaceutical companies are sharply aware of this fact. Therefore, in analyzing and making healthcare policies, this fact should play an equally significant role.

As we show in more detail in the next section, the profits of (especially) the big pharmaceutical industries and their shareholders are often excessive. A major cause of these excesses are the strong commercial monopolies granted to the pharmaceutical industry through their patents. Most of the economic studies we discuss are (rightly) critical of the current system of drug production. Yet, it is often the case that the crucial role of patents is not adequately analyzed or acknowledged. Two key factors explain why these patents lead to huge profits and high drug prices. First, the often comprehensive monopolies create a powerful market position for their owners. Second, this strong position significantly weakens the negotiation space of governments and governmental agencies.[6] They need to negotiate with pharmaceutical companies about the reimbursements these companies will receive for the drugs they deliver. It is true that governments around the world have been trying to reduce the (growth of the) costs of medicines for decades.[7] In spite of this, as specified in the next section, drug prices have continued to rise to amounts that already are, or will soon become, definitely unsustainable.

In addition, some general features of the theory and practice of patenting reinforce these conclusions. Overly broad patents inappropriately extrapolate the significance of the inventions on which patent applications are based and thus strengthen the monopolies of the pharmaceutical companies. Seth Shulman's (1999) book *Owning the Future* still offers an eye-opening (if also depressing) critique of the unjustifiable broadness of a host of approved patents. The many product patents grant their holders an even stronger protection. They provide an exclusive right of commercially exploiting the product as produced by *any* (known or, as yet, unknown) process. Thus, the holders of a product patent are rewarded for an unspecified range of hypothetical inventions, which they have not actually made available. Therefore, the protection awarded through a product patent can never be "sufficiently supported by the description of the actual invention," as is required by patent laws and regulations. In fact, product patents effectively patent a concept and hence they are illegal (Radder 2004, 283–286). Finally, pharmaceutical companies employ a number of tactics to expand their monopolies beyond the usual patent validity of twenty years. For instance, by re-patenting a drug on the basis of "improved formulations," "new indications" or "combinations with another drug" (Van der Gronde et al.

2017, 12). A consequence of these thus strengthened monopolies is a substantial weakening of the negotiation space of the public stakeholders.

Our conclusion is that we urgently need to break away from the current system of drug production and work toward a system of medical research without patents.[8] Keep muddling through with inadequate conventional policies will only aggravate our problems. There are, moreover, precedents for significant revisions of the patent system. A prominent example is the ruling of the Supreme Court of the US in 2013 that isolated human genes are not patentable because they are products of nature (see Parthasarathy 2017, 156–171). We think that it is high time for a comparable revision regarding medical patents.[9] As explained in the next section, a significant part of our argument for abolishing drug patents stems from its economic and financial advantages. This distinguishes our approach from the many criticisms of patenting life forms, which are often exclusively of a moral nature (see the extensive discussion in Parthasarathy 2017). In a series of publications, James Brown has consistently argued for eliminating medical patents (see, e.g., Brown 2008, 209–211). But he has not addressed in any detail the economic and financial profitability and the socio-political and organizational practicability of abolishing these patents. It is these topics that are discussed in the following two sections. Section 2 shows that eliminating medical patents could lead to greatly reduced prices of prescription drugs. In section 3 we make a proposal of how such a change could be concretely and effectively realized.

2. Medical research without patents: It's profitable

In this section we discuss a range of pertinent economic and financial features of the current system of drug production. Our review draws on several in-depth studies of the relevant issues. As in the preceding section, its aim is to demonstrate the urgency of a significant change of our healthcare policy and to offer strong and convincing reasons for starting serious study and debate on practicable alternatives. The presented economic and financial figures are mostly of a general and approximate nature. Of course, when thinking about the implementation of a concrete alternative, additional detail will be required. But given these general results, we fail to see what further reasons would be needed to start the study and development of an alternative system of drug production.

Over the past decades, in many countries healthcare expenses have multiplied. By way of example, we briefly consider the Netherlands and the United States. As representative countries of the wealthy parts of the world, the following figures provide a rough estimate of the development of healthcare expenses in comparable countries during the past decades. At this stage of our argument, the purpose is to provide some approximate background

information about the recent financial developments of the relevant drug production systems. Concerning the growth of healthcare expenses as a percentage of the Gross Domestic Product (GDP), the Netherlands Scientific Council for Government Policy (a prominent advisory body of the Netherlands Government and Parliament) concludes that

> average government expenditure on healthcare has been growing faster than overall income since the 1970s. … Under existing institutions, incentives and budgetary mechanisms, total healthcare expenditure is expected to increase from 12.7% of GDP in 2015 to well over 20% by 2060. In absolute terms this amounts to a threefold increase in healthcare costs per capita. (De Visser et al. 2021b, 10)

To obtain a more concrete idea about the rate of this growth, consider the healthcare expenses per capita per year. Corrected for inflation, for an inhabitant of the Netherlands these expenses have increased from about €2000 in 1970 to about €6000 in 2015 (De Visser et al. 2021a, 78). Furthermore, on average, the member states of the Organization for Economic Co-operation and Development (OECD) spend 17% of their healthcare budgets on pharmaceuticals (Van der Gronde et al. 2017, 3). Therefore, a rough estimate of the trend of these expenses per capita in the Netherlands amounts to an inflation-corrected growth from €340 in 1970 to €1020 in 2015.

In the US, the growth of the costs of prescription drugs shows a similar pattern. In 1980, they amounted to about 0.4% of the GDP; in 1993 they had risen to 0.8% and in 2022 to 2.1% (Baker 2022, 280–281).[10] Moreover, while this percentage had been mostly constant between 1959 and 1980, its sharp rise after that period coincided with the acceptance of the Bayh-Dole Act in 1980. This Act allowed the acquisition of patent monopolies on research results funded by public money. Baker (2022, 281) concludes that "there can be little doubt that this change in the law governing control of government research hugely increased our spending on prescription drugs."

Moreover, as noted in the previous section, this excessive growth of both total healthcare expenditure and the overall costs of pharmaceuticals has continued in spite of a variety of persistent attempts by governments to curb these expenses. No wonder that time and again, politicians, medical organizations and healthcare analysts have emphasized that the continuing increase of these figures will make our present system of healthcare and prescription drugs fully unsustainable in the future.

Especially relevant for the purpose of this article is a range of more detailed findings about the financial aspects of the third and fifth stage of drug production. In their extended study, Toon van der Gronde, Carien Uyl-de Groot and Toine Pieters review and document the following facts. For a start, there are many examples of highly or even excessively priced drugs.[11] An important point is that these high prices

cannot be accounted for by the real R&D and manufacture costs of the pharmaceutical industries, for two reasons. The first is that huge amounts of money are spent on marketing. "In fact, more money is spent on marketing than on R&D" (Van der Gronde et al. 2017, 10). Second, the drugs are seriously overpriced because a disproportional part of the income of these industries consists of excessive profits for the companies and their shareholders. "On average, the top ten pharmaceutical companies have a profit margin of 20%; … those noted in the S&P1500 have a net profit margin of 16%, compared to 7% for all other companies in the index."[12]

Comparable conclusions have been drawn by Rodrigo Fernandez and Tobias Klinge. They have scrutinized the financial accounts of 27 of the world's largest pharmaceutical corporations, in the period between 2000 and 2018. Their report about the financialization of these companies includes the following results.

> Total payouts to shareholders (dividends and share buybacks combined) have increased from 88% of total investments in research and development (R&D) in 2000 to 123% in 2018. In nominal terms, payouts to shareholders have increased by almost 400% – from US$30 billion in 2000 to US$146 billion in 2018 (US $73 billion in dividends and US$74 billion in share buybacks). This represents a rise in the share of payouts from 10% of net sales to 20%.[13]

A recent study by Aris Angelis and colleagues adds further relevant data, which display a similar pattern.

> Based on publicly available financial reports from 1999 to 2018, the 15 largest biopharmaceutical companies had total revenues of [US]$7.7tr. Over this period, they spent [US]$2.2tr on costs relating to selling, general, and administrative activities – a category that includes marketing and advertising, as well as almost all other business costs not directly attributable to manufacturing a product or performing a service – and [US]$1.4tr on R&D. (Angelis et al. 2023, 1)

The general conclusion is that such excessive profits are indefensible and unaffordable in a context of aging societies and permanently increasing healthcare expenses. Drug prices worldwide are unnecessarily high and cannot be justified.

Finally, consider the analysis by Dean Baker. He rightly states that patent monopolies are tools of (national or international) public policies; they are not based on laws of nature or technological necessities. For this reason and given the huge problems of current practices, attempts to construct alternative policies of drug production are fully justified.[14] In this spirit, he has calculated the approximate public savings on prescription drugs that could be had by the US in a world without patents and patent-related protections (Baker 2022, 284–287). Starting from

a plausible average price for generic drugs of 50% of the current price, he concludes that more than 85% of current spending could be saved in a patent-free world.

There is an important proviso, however, because not all of these savings can be realized in an appropriate system of drug production. Baker adds:

> The savings would include not only the profits lost to the sellers but also a wide range of costs associated with these protections, such as legal fees, marketing to maximize the profit of an item on which the company has a monopoly, and *payments for the actual innovation or creative work*. (Baker 2022, 286, our emphasis)

Of course, an alternative system of drug production without patents would also have to include the necessary expenses for the actual innovations.[15] As we argued in section 1, a significant part of these expenses is already paid by the public. Yet, a remaining sum for these R&D activities will be required. In the next section we will argue that, in a system without patents, these remaining costs can be funded by a limited surcharge on prescription drugs, to be paid either directly by individual purchasers of the drugs or indirectly by insurance companies.

As mentioned in the previous section, claims about the R&D costs for medicines vary widely. Van der Gronde et al. (2017, 8) mention an extreme of US$ 2.6 billion, but conclude that most estimates amount to about US$ 800 million for one potential drug "from research bench to prescription drug." Brown (2008, 210) argues (rightly, we think) that the usually included marketing costs are not part of genuine research, and therefore he claims that something like US$ 100 million is more sensible. Of course, if applied to 2024, these estimates need to be corrected for inflation. The important point here is that these R&D expenses are not part of the three major cost-cutting policies on which our proposal is based. What *is* a part of our proposal is that, in line with current values of open science and responsible innovation, the calculations of these costs need to be fully transparent. If transparent calculations of the R&D expenditure prove to be lower than what the public is charged for through the current drug prices of the pharmaceutical companies, this constitutes a further bonus of our proposal.

To get an intuitive idea about the strong reduction of the average price of prescription drugs in a patent-free system, consider the following tentative example. In 2021 pharmaceutical company Pfizer achieved a profit of US$ 21.9 billion (Kreling 2022). Suppose that this profit had been reduced with two-thirds from US$ 21 billion to US$ 7 billion (thus, following the above-quoted figures, from an excessive profit of 20% to the average profit margin of about 7%). This would have made available a public saving of US$ 14 billion. In addition, in a system without patents two further savings on Pfizer's medicines could have been accomplished. First, because of the

dropping of the substantial expenses and fees of Pfizer's patent practices; second, because no (or far less) money would have been spent on its advertising and lobbying activities (which is often more than what is spent on R&D). In line with Baker's conclusion, these three substantial cost-cutting consequences of abolishing patents could have resulted in a very strong reduction of the prices of Pfizer's drugs.

Of course, this example is heuristic and preliminary. Yet, together with the other economic and financial studies discussed in this section, it emphasizes the desirability and profitability of replacing the current system of drug production by a patent-free system. For this purpose, it is important to realize that patent laws and regulations have often been subject to smaller and larger changes. A major illustration is the introduction of the European Directive on the legal protection of biotechnological inventions at the end of the last century (see Sterckx 2000). Moreover, the patent systems of different countries or regions are not identical. Despite their apparent uniformity, the world's patent systems display "key differences in legacies, makeup, and dynamics" (Parthasarathy 2017, 21). This implies, for instance, that patents that are valid in the US are not automatically valid in Canada, Europe, India or China, and the converse holds as well. It also means that changing patent policies may start in particular countries or regions. The obstructive objection that we first have to await a worldwide consensus on the relevant changes can be legitimately bypassed. If, say, Canada, India and the European countries abolish medical patents, in these countries US patents will not be valid anymore and reasonably priced generic copies of the expensive US drugs will be available there. The remaining task, undertaken in the next section, is to show that, and how, realizing such a patent-free alternative is socio-politically and organizationally practicable.

3. Medical research without patents: It's practicable

This final section makes space for a thought experiment, an alternative research policy that we use to think through the implications of a world in which there are no patents on drugs. We do not pretend that what we say in this section will be the last word on this subject. Of course, further study and debate on its practical implementation are needed, for instance on relevant differences between countries. What we do claim, however, is to have demonstrated the urgency of starting such study and debate, preferably today rather than tomorrow.

Complaints about high drug prices and the behavior of pharmaceutical companies are piling up. At the same time, there is a feeling of powerlessness in society: we need these monopolistic companies, but hopefully we can keep them in line, even if, regretfully, we are at the mercy of their whims and the financial interests of their shareholders. It is high time to break through this

societal feeling of powerlessness. We cannot escape the question of whether the pharmaceutical industry, as it exists today, will ever be acceptable. In fact, the following essential question is in order: do we still need these companies? The answer is no. Developing drugs for new disease variants requires research. To achieve this, we do not need the current pharmaceutical companies per se. That research can be done at universities or by other independent research institutes, as is (in part) already happening. Of course, this has to be paid for and we will propose a solution for this financial issue.

To fund research into new medicines, let us imagine that a country establishes a Pharmaceutical Research Funding Agency (PRFA), financed with substantial public funding. We return below to the question of where that money should come from. One could imagine this PRFA taking on a semi-public character, but how exactly is a matter of further debate. Independent committees within the PRFA consist of people from the medical community and from society at large, and they select the medical projects for which research funding will be available. It is important that the committees remain at arm's length from the government. These PRFA committees determine which research institutes will conduct relevant research, including the testing of possible drugs. This approach relates not only to diseases that present themselves acutely, but also, for example, to pandemics that might occur in the future. The research assignments may involve both basic and application-oriented research. What we call alternative medicines, vitamins and other treatment methods could also be included in such research. The assignments can be of two types: tenders, as formulated by the PRFA, and also bottom-up proposals as defined by already existing research institutes and their researchers (what we label "open calls").

The PRFA committees are going to issue tenders and open calls. Both university and commercial laboratories may bid for those. If they possess the relevant knowledge, independent research spin-offs of the current pharmaceutical companies may also bid. The big difference from the current system is that, if their bid is successful, they will be paid to do the research and testing – nothing more – and after that the acquired knowledge may be freely used. Compared to the current situation, there is a reversal of dependency relations. It is the PRFA and its committees, not the pharmaceutical companies, which control the setup and assessment of submitted research projects.

To avoid misunderstanding, this proposal is not calling for a state-owned pharmaceutical industry. Every laboratory and every research institute – academic or non-academic – may consider the research calls issued by the committees of the PFRA. In that way there will be plenty of competition. The various committees may decide to award research funding for a drug to a few applicants with different research approaches. These applicants can, and should, communicate with each other about their interim findings, in order to enrich each other's research.

All knowledge resulting from this research and its possible uses should be publicly and freely available. Patents are no longer involved. As shown in the preceding sections, current research policies have created a situation in which the big pharmaceutical companies own most of the patents on medicines. Both the high costs of acquiring and defending the patents and the resulting monopolies from acquired patents have resulted in highly overpriced drugs.

Let's return to our thought experiment: we have eliminated patents on medicines. We then place the relevant knowledge in a Pharmaceutical (or Medical) Commons to make it a genuine common good. In principle, this knowledge may be used by everyone. But in the case of the actual uses of medicines we need to place scientific, social, economic and moral constraints on how, by whom, and under what conditions that knowledge may be used. Commons are always regulated, as they should be. This fact is immediately important when, with that knowledge in their pockets, manufacturing companies will start to produce pills, powders, potions, vaccines, and the like.

In itself, there should be no restriction as to which companies can do that, but there must be a package of conditions. Obviously, national or international regulatory agencies, such as the FDA and the EMA, have to approve the quality of what is produced. As we have explained in the previous section, the manufacturing companies will be able to deliver their products to hospitals and pharmacies at strongly reduced prices – with a reasonable, modest profit. The fact that the knowledge used by these companies has been acquired with public money and regulated by public institutes is a further reason that justifies the setting of a modest price ceiling. A corollary condition is that the price calculations must be completely transparent. To the question "will there be enough drugs available in a patent-free world?" the answer is "why not." Doing business at a modest profit is the rule, not the exception. As in the current system (and similar to the energy transition politics), it will remain the task of government policies to advance non-monopolistic competition by counteracting the occurrence of one-sided dependencies on a single drug provider.

We have now arrived at the point – to bring it sharply into focus once more – where the funding and selection of research projects is the responsibility of the PRFA, while the manufacture is done basically at cost price. This means that drugs will henceforth be available in hospitals and pharmacies, and thus to the patients, at a decent, strongly reduced price. Of course, this substantial price drop will have a more than beneficial effect on healthcare costs. On the medication side, these costs will be significantly reduced. Moreover, these medicines have been produced from a social and healthcare interest, paid for collectively by us as citizens. We have strongly reduced the unjustifiable weight of shareholders and marketing expenses.

Now the time has come to ask the pressing question of how the Pharmaceutical Research Funds will be filled with substantial amounts of

money. There is an answer to that question. What we will do is the following. On top of the set price of the prescription drugs we levy a surcharge. This surcharge can be either paid directly by the individual purchasers of the drugs in hospitals or pharmacies; or it can be paid indirectly by increasing the premium of the health insurances and have the health insurance providers finance the Research Funds. After all, in our proposal the drugs will be substantially cheaper, so the costs of health insurances will diminish accordingly. The resulting funding will be used to replenish the Research Funds for the purpose of new medical research and development. We, as a society, will use these crucial surcharges to finance the research we want.

From an economic perspective, we can compare what we now, in the current undesirable situation, have to pay at the pharmacy, with a tax: you have to buy the overpriced medicines, since there is no or hardly any alternative. Therefore, this constitutes a kind of tax as well. But then the fundamental principle "no taxation without representation" should apply. With our surcharges, we ourselves contribute to the PRFA, where people from the medical world and other societal stakeholders decide for which research the money will be used.

How much money does the PRFA need to ensure that sufficient short- and long-term research, for various types of diseases and disorders, can be broadly funded? In section 2, we provided a tentative example showing that, in a world without patents (such as those of Pfizer), substantial public sums will become available. But of course, further economic research is needed to answer the question of how much funding is required each year to finance the necessary research, including all the relevant tests. If we know that, then we can calculate the required public funding through the surcharges on the price of prescription drugs.

Of course, what we are proposing can only begin if at least a significant number of countries participate. That will require some persuasion and missionary work. Consider, for instance, the European situation. The pharmaceutical industries based in France, Germany and Switzerland will not let this happen silently. For the pessimist – looking at the current situation – our proposal is already a lost cause. But it does happen sometimes that David defeats Goliath. For example, in a recent court case in the Netherlands about climate issues, *Milieudefensie* (Friends of the Earth) beat oil giant Shell (Khan 2021; see also Burgers 2020). The fact is that public opinion against pharmaceutical companies' abuse of their monopolistic position certainly creates opportunities.

Let us go further with our thought experiment. Suppose we get to the point where Europe is in the starting blocks for a radical transformation of its drug production system: we have placed the relevant knowledge, financed by the PRFA, in a Pharmaceutical Commons. In principle, because of its free availability, it might still be used by the existing pharmaceutical industries to

produce and sell drugs at their usual overpriced rates. In practice, however, in the new situation of non-monopolistic competition they will be quickly outdone by new producers that use the cheap, freely available pharmaceutical R&D knowledge to supply drugs at much lower rates.

Of course, in order to develop medicines for new diseases, it must also be possible to make use of knowledge already available in society. The problem that arises here is that the uses of much of that knowledge are already privatized through patents by the present pharmaceutical companies. From our perspective, these patents should never have been granted, but they have been, and we still want to use this knowledge. The best option to tackle this problem is to apply compulsory licenses. This procedure has been repeatedly and increasingly used (primarily in Europe) in a variety of social controversies concerning the patenting of life forms. "Responding to concerns that patents on human genes might hurt access to testing and therapy, many countries amended their compulsory licensing laws in the early 2000s" (Parthasarathy 2017, 186). A second (but less attractive) option is to expropriate the patents, for a reasonable fee. In other sectors, there are many examples of governments compensating individuals and companies when undertaking new projects in the public interest. There will be some wrangling about the size of the fees, but that can be worked out. Questions that will arise include, for example, how many years certain patents will still be valid and what their real value is (in contrast to the value inflated by the present pharmaceutical companies).

Although this new research policy may require substantial short-term investment, that would be easily cushioned because, in our analysis, drugs will become substantially cheaper at the pharmacies. Of course, we must also ensure that the incumbent pharmaceutical companies pay taxes on their compensation. That is something they, with their epidemic tax evasions in mind, have yet to learn.[16]

One of the many benefits of this proposal is that it puts a brake on the spread of illegal drugs. Worldwide, there are many drugs in circulation, often of questionable quality, or just plain fake. This is a catastrophe for public health. But when the prices of medicines will be considerably lower than they are now, the demand for cheaper drugs will decline (see Naím 2006). Of course, not all illegal drugs will disappear, but the incentive to offer illegal pills, potions and powders over the internet will diminish. The illegal market can hardly compete with the reasonably priced drugs that will be available at pharmacies after the abolishment of patents. This is another gain for public health.

A further benefit is that the uses of pharmaceutical knowledge will no longer be privatized. Henceforth there will be a large reservoir of insights available on which future researchers can freely build. Equally important is that knowledge about failures and unsatisfactory outcomes of research will

become publicly known. Much current research leads, seemingly, to nothing. That's part of the game. But knowledge about failures is rarely published even though it can be extremely useful. Knowledge of a failed research project can help put another research group on a track that does lead to useful results. Medical and pharmaceutical research groups at universities will have to get used to the fact that they no longer have to operate in a commercial market. In the current situation they often have to resort to secrecy in order that their patentable research results can be sold to pharmaceutical industries. After all, that is the common earning model of their research institutes. In the new situation they can simply compete for the research funding provided by the PRFA, where they can also propose projects for follow-up development and implementation of their research results.

It is widely acknowledged that serendipity, the stroke of chance, sometimes produces ground-breaking results. The more freely shared knowledge there is, the more likely it is that happy coincidence can strike. Because of this unpredictability, it is advisable to provide long-term funding from the Research Funds to a number of research laboratories that specialize in certain areas. Teams of researchers working together over long periods of time can produce extraordinary results. Expertise is not only the result of training. It must be nurtured and allowed to thrive in collaborations where people can learn to work together. This requires continuity and stability.

The main difference with the research laboratories of today's pharmaceutical industries is that these labs focus on types of knowledge and inventions that are exclusive, patentable and can be brought to the market, with the aim of producing medicines for which a substantial market exists or can be created. In our proposal, even in the case of the long-term funded research institutes, this exclusivity does not exist, quite the opposite. The primary goal is not to focus on markets and shareholders, but on the health interests of different countries and different groups within a country, poor and affluent. That is why the long-term funded research laboratories must keep reporting the progress of their research to the PRFA. Still, within this constellation there should and will be ample room for the unexpected, the pharmaceutical gems that people did not know they needed, but which suddenly emerge as a "gift" for the well-being of public healthcare.[17]

How does such long-term funding relate to the tenders issued by the PRFA, as described above? To make this connection two things need to go together: the specific requests for medicines from society and the independent research programs of the research laboratories. Of course, research laboratories without long-term funding can and will respond to the tenders from the PRFA. Increasingly, these often smaller institutes prove to bring about significant innovation. When smaller university institutes or research laboratories without long-term funding are on the road to a major discovery,

better-equipped institutes are needed for further development and testing. These could be the larger long-term funded laboratories.

In this section, we talk about the PRFA committees, in the plural. It remains an open question whether there should be just one, large Research Fund, with several departments, or whether the establishment of several Funds is more appropriate. Of course, this is not the only question raised by our policy proposal. It should be possible to free ourselves from big pharma and to return medicine to the public domain. That much is clear. But at the same time we are aware that there is a long road ahead of us, with many obstacles.

If we follow this proposal and make the big pharmaceutical companies superfluous we will solve several pressing societal problems. Healthcare will no longer be primarily subservient to shareholders and will become more affordable. All the research needed to develop medicines will no longer be surrounded by patents, but will return to public ownership. The most essential part of our proposal is that access to medicines will once again become a human right, and no longer the plaything of big pharma's shareholders. The arguments in the first two sections and the thought experiment in this final section demonstrate how such a shift in our healthcare system could be scientifically, socially and morally preferable, economically and financially profitable, and socio-politically and organizationally practicable.

Notes

1. In this article, we advocate a particular change that will advance the public interest of our healthcare system. For a more comprehensive account of "the public interest of research," see Radder (2019).
2. Note that proponents of this view may admit that, in *particular* cases, patents can be a source of bias (see, e.g., Resnik 2007, 152–153; De Ridder et al. 2023, 278).
3. See, e.g., Krimsky (2003); Resnik (2007); Brown (2008, 2016); Musschenga, Van der Steen and Ho (2010); Cosgrove et al. (2016); Sismondo (2018); Baker (2022); Pieters (2023).
4. More specific quantitative results may be available, though. Two examples: In 2023, the United States government spent almost US$48 billion on medical research through the National Institutes of Health (see https://www.nih.gov/about-nih/what-we-do/budget) and several billion more through other government agencies. In addition to the funding organizations of its member states, the European Union also devotes substan tial public resources to developing drugs through a range of different funding schemes. One of those, the Horizon 2020 program, supported a great variety of biomedical and health research projects with about 8 billion euros (Gallo et al. 2021, 1211).
5. Robinson (2019, 4399). On this topic, see also Dosi et al. (2023, 23–26).
6. An important further reason for the weak "market position" of public stakeholders is that the drug market is by no means a free market. Because of their vulnerable condition of suffering and being in pain, the options available to its primary "consumers," the patients, are often strongly constrained. By implication doctors,

pharmacists and insurance companies are similarly constrained. They cannot simply tell a supplier that they will not buy its drugs because they are too expensive.

7. See the extensive discussion and evaluation of sixteen different kinds of attempted policy regulations in Van der Gronde et al. (2017, 13–24).
8. The incompatibility of commercial patenting practices with ethical codes of academic research offers additional support for discontinuing this kind of engagement of academic researchers in the pharmaceutical industry's pursuit of profit (see Radder 2022, 2023; De Ridder et al. 2023).

   Although the focus of this article is on the patent practices of big pharmaceutical companies, generally abolishing medical patents will also put an end to patenting, and hence privatizing, the results of publicly funded medical research (for pertinent criticisms of academic patenting, see the contributions to Radder 2010).
9. In this respect, Van der Gronde et al. (2017, 21) have too quickly accepted the argument of the impossibility of abolishing medical patents as discussed at the start of this section.
10. In terms of the drug prices themselves, see the analysis of the strongly increased prices of newly-marketed prescription drugs in the US between 2008 and 2021 in Rome, Egilman and Kesselheim (2022).
11. As a matter of fact, US prices of prescription drugs are among the highest. While its policies are often justified by a belief in a free market, the real pharmaceutical market is based on monopolistic strategies rather than on cost-effective free competition.
12. Van der Gronde et al. (2017, 12).The S&P1500 is a market index of US stocks made by the company S&P Global.
13. Fernandez and Klinge (2020, 5). Note that these figures do not yet include the record profits large pharmaceutical companies have made during the COVID pandemic. For instance, in 2021 the pharmaceutical company Pfizer achieved a profit of US$ 21.9 billion, its highest profit since 2014 (see Kreling 2022).
14. An option briefly discussed (Baker 2022, 293–294, note 12) is the direct public funding of the first three stages of drug production.
15. That medical patents often contribute to therapeutically significant innovation is a disputed claim. Giovanni Dosi and colleagues, for instance, conclude that "taking stock of a long-term empirical evidence on the pharmaceutical sector in the US, we can hardly support IPRs [that is, Intellectual Property Rights] intended as an innovation rewarding institution. According to our analysis, pharma patents have constituted legal barriers to protect intellectual monopolies rather than an incentive and a reward to innovative efforts." Dosi et al. (2023, 15); see also Angelis et al. (2023, 3–5).
16. See https://www.oxfam.org/en/press-releases/drug-companies-cheating-countries-out-billions-tax-revenues.
17. For further discussion of the public interest of supporting such basic research, see Radder (2019, 218–224).

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