Measuring the differences between two "identical" products: The case of generic drugs in France

Abstract:

The mainstream economic theory generally assumes that the characteristics of the products are obvious for the consumer who can choose between any given product on the basis of prices and preferences. This simplistic presentation of product qualities is discussed by many researchers in socio-economics through the theme of measurement: How are qualities evaluated? What role do physical characteristics and price play in such an evaluation? These questions are particularly striking when the compared products are presented like identical in composition, as it is the case for the generic drugs in France. The French authorities legally defined the generic drug as identical in essence to the original drug but a myriad of small differences remain in its presentation. The consumers are assured that it is the same thing while it doesn't look like the same thing. Who must they trust to measure the differences between generic and original drugs: the composition written on the box ? the doctor or the pharmacist? their own body? This question is all the more important as in the field of health self-realizing prophecies are numerous. In this paper, we would like to analyze the way in which the actors on the health field (especially pharmacists and patients) discuss the best way of measuring economic and physical differences between generic drugs and original drugs.

Measuring the differences between two "identical" products: The case of generic drugs in France

The question of product quality has become a key question in economic sociology, as it seems in some ways to overstep the bounds of mainstream economics. The mainstream economic theory generally assumes that the characteristics of the products are obvious to the consumer, who has a choice between any given set of products on the basis of prices and preferences. This simplistic presentation of the issue of product quality is discussed by many researchers in socio-economics through the theme of systems of measurement: How are qualities evaluated? What role do physical characteristics and price play in such an evaluation? These questions are particularly striking when the products compared are presented as being identical in composition, as is the case concerning generic drugs in France.

In this paper, we shall analyze the interaction that takes place when patients choose between an original drug and a generic drug in a pharmacy, beginning with an everyday life situation: for the first time, a pharmacist offers a patient a generic drug instead of the drug prescribed by his or her doctor. This patient, faced with a "new" product, will probably wonder about its physical specifications and discuss the similarities and differences between the two products with the pharmacist. The French authorities have legally defined the generic drug as identical in essence to the original drug, but a myriad of small differences remain in its presentation. The patient is assured that the products are identical; however, they do not appear to be the same. Who and what must be trust to measure the difference between generic and original drugs: The word of the pharmacist? The ingredients written on the box? His own body? His experience with other markets? In order to answer such questions, pharmacists and patients must try to find a common system of measurement, which would truly allow us to compare a product with its (almost) exact copy. As they search for this common system of evaluation, they are induced to position themselves on a field of more general problems. Do they believe in the capacity of State, Science and Industry to produce an exact copy? What is price supposed to indicate, and how do they explain price difference between the products?

The objective of this article is to show how pragmatic comparison in an everyday life situation supposes a general system of measurement, i.e. a set of beliefs (in the rules of Science, State and Market), which will enable comparison. The presentation will be divided into three parts: First, we will see that the comparing of products in a French pharmacy is not

a simple matter, since most drugs are not accessible to or even seen by patients. Thus, most of the time, patients can't really determine for themselves the differences or similarities between original and generic drugs. We will then study how pharmacists and patients negotiate the relevant way to compare the two drugs. The second part of the text will deal with the physical specifications of generic and original drugs. It seems that the comparison of these specifications opposes two types of measurement systems: on the one hand, most pharmacists insist on the fact that State, Science and Industry guarantee the exactitude of the copy; on the other hand, some patients appeal to their senses and their common sense in asserting their conviction that there are many real differences between the two products. Finally, we will analyze the role played by price in the evaluation of the value of generic drugs. We will see that price can either counteract or reinforce doubts about the identity of the products, depending on whether patients (and the pharmacist) believe in the capacity of the pharmaceuticals market to promote the "real" price of drugs or fear that the difference in price hides a difference in quality.

This paper is the result of a study directed by F. Vatin at the University of Paris-X Nanterre. More than the reporting of verified results, this paper intends to lay the foundations of my PHD research project. This research takes place within the works of the "MESURE" group¹, which leads a reflection on the role of calculation, particularly market calculation, in the construction of modernity.

The pharmacy: A place propitious to comparison?

Before entering the core of the question, I would like to describe the framework in which the comparison of the products takes place. The French pharmacy is a very specific marketplace since the products sold can have very serious consequences on patients' health. This is the reason why most products are not directly accessible to patients. The question is, then, quite simple: "How can patients really compare products, if they can't reach or even see them?"

When a patient enters a French pharmacy, his surrounding environment is composed of "parapharmaceutical" products. These products are not considered "real" drugs, insofar as their misuse would not have serious negative side effects on patients' health and since they are not reimbursed by Social Security. This is why patients have direct access to them. The

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¹ http://www.u-paris10.fr/16413252/0/fiche___pagelibre/

display of these products is identical to that observed in supermarkets. Patients can freely compare every aspect of these products: physical specifications, price, etc. When the patient approaches the counter, he is standing directly opposite "over the counter" (OTC) drugs, i.e. drugs he can buy without a prescription (and without a Social Security refund), just behind the counter. These products are considered "drugs" since they can have negative side effects on patients' health, yet their effects are judged too weak to necessitate a prescription. These products are not directly accessible to patients, but they can be seen. This provides the patient with an imperfect set of information including such things as price and the general shape of the box. In any case, these products are well-known to patients. ² However, these two first types of products are not concerned by competition with generic drugs. The third type of drugs concerns reimbursed drugs, which require a prescription to be sold. For reasons of public health, these drugs are kept in boxes behind the counter. They must not be purchased or seen by patients without medical and pharmaceutical allowance.³

Almost all generic drugs in France belong in this third category. How can patients compare generic and original drugs if these products escape both their reach and sight? Patients cannot independently and directly perform the complete comparison between these products, basing themselves on information provided on the box, that they would be able to in a supermarket. The set of information that states and industrials have elaborated to facilitate the comparison between generic and original drugs is not directly accessible. The pharmacy space isn't a space of perfect information. On the contrary, it is built on opacity as a guarantee of public (and personal) health. The pharmacist is inserted in between patients and drugs, and he can manipulate his position in order to reveal or hide differences and similarities between the original and generic drugs according to his interests. He can pressure the patient to believe him on the value of his word and choose between products without ever having seen them. In this situation, which is most frequent, the patient is not in control of the comparison.

This can explain the fact that, most of the time, patients don't know the real differences between generic and original drugs, especially the difference in price. This ignorance of price is extremely paradoxical, as it should theoretically motivate their choice of the generic drug (see part III). The problem is that they cannot really compare the prices of these drugs so long as they are kept hidden. Thus, they know, at best, the price of the drug

² The most popular of these drugs is Paracetamol, but there are some others. These drugs can be reimbursed if prescribed, but they don't require a prescription to be sold.

³ There are also practical reasons that explain such a choice. Since these products cannot be directly purchased by patients, they don't need to be presented. The pharmacist can stock these products in the back of the shop, which is clearly a gain of space.

they have chosen. But even in this moment, they can ignore the price due to the "Third-party-payment" system. Through this system, which affects 92 % of the sales in pharmacy⁴, the patients do not need to advance the sum to pay for the drugs. They simply give their "Vitale Card", and they only have to pay the (small) portion of the drug price that is not reimbursed by Social Security or their private health insurance. This spatial and temporal separation between buying and paying plays an important role in the ignoring of drug prices.

The patient can nevertheless investigate from his own home if he has the prescriptions and boxes of both types of drugs. But this seems to be an important time investment that few patients really make. The patients who want to make a real comparison ask the pharmacist to show them both products. The pharmacist himself can also decide to show both products to patients, either because he's asked to do so or because he thinks it could support his argument.⁵ This second option is problematic as it costs pharmacists time and energy. It could also be psychologically costly, as the pharmacist is exposed to a refusal from the patient, while he has spent time performing the comparison. This is why pharmacists rarely choose this option. Two requirements must be fulfilled in order for this investment to be advantageous. First, the pharmacist needs time to make a proper comparison, which depends on the crowd and queue in the pharmacy. The pharmacist can also use this pretext to lead the choice in a direction that satisfies him. Second, the pharmacist must believe that the generic drugs will benefit from the comparison in the short and long term. Both conditions are not always present, and the pharmacist can have all the more interest in maintaining some obscurity about the comparative specifications of the products if he believes that differences (of specifications and prices) will not be very convincing to the patient.

As we can see, the space-time characteristics of the pharmacy seem to set up harsh difficulties for a comparison of generic and original drugs in every sense. Most of the time, the patient can only carry out this comparison when he consumes the drugs. If the construction of opinions on generic drugs is done in the pharmacy, it's often only through hints and without the support of the products.

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⁴ Cf. annex 17 of the « Rapport HCAM », p.82.

⁵ We will come back on that point, but we can already say that the pharmacist

"Is it the same?" Measuring identity between two products

A patient goes to his pharmacy with his prescription on which his doctor has written the brand name⁶ of a drug that the patient is used to taking regularly (for example antihypertensive) and the name of a more exceptional or case-specific drug (for example antibiotics). The comparison between generic and original drugs will, of course, depend on the habits of the patient, his knowledge of the drugs, the importance of the drug for his health and his former experiences with generic drugs. Pharmacists know this and rarely propose to substitute generic drugs for the whole prescription. They usually begin with exceptional drugs that the patient doesn't know very much about and which are not vital for him on a regular basis. Since December 1998, pharmacists have the right to substitute, with the agreement of the patient, a generic drug for the original drug written on the prescription as soon as this generic drug is registered in the Official Repertory of generic drugs.

Substitution is posing important problems, however, as it can be perceived as a break with the classical care relationship. It sets the written word of the doctor against the spoken word of the pharmacist. In order to maintain the continuity of the prescription, while there is a substitution of the products, pharmacists must convince the patients that the substituted products are the same. For this reason, practically every interaction in the pharmacy begins like this: "Instead of your X, may I give you a generic drug? It's the same thing." The objective if this part of the paper is to analyze the way in which a typical interaction is built on this question of substitution. Which arguments are advanced? On what written information or support, and on what comparison methods are these arguments based? In this part we will only discuss the physical specifications of drugs. We will then devote the third part to the question of drug prices.

First, let's consider the supports at the pharmacist's disposal in defending the claim of identity between generic and original drugs. Most of the time, pharmacists merely assert that both drugs are the same in composition without discussing this assertion any further. They rely on the idea that the trust relationship between pharmacist and patient should be enough to obliterate the patient's doubts. While this authority position can reassure patients that are already convinced, it isn't powerful enough for patients who haven't already experimented

⁶ The original drugs have, most of the time, a trademark name. Generic drugs can also have a trademark name but most of the time their name is created according to the International Common Denomination (ICD), which is the name given by the World Health Organization to the active molecule in the drug. Even if the French doctors have committed themselves to writing ½ of their prescriptions in ICD, the actual rate is 10-12 %.

with generic drugs or who lack confidence in pharmacists' opinions. The pharmacists must often develop their ideas and enter into the details of the making of generic drugs.

One of their supports in arguing is the law. Since 1996, generics are legally defined as drugs that are identical to the original in quantitative and qualitative composition, in pharmaceutical form⁷ and in their diffusion in the organism (bio-equivalency). The generic drug is then legally defined as essentially identical to the original drug. Moreover, a State agency (the "Afssaps"⁸) is in charge of guaranteeing the law. It must register the drugs on the Official Repertory and control the conformity of the manufacturing process and the final products. The ensemble of these official actions is concretely summarized in the inscriptions on the box of drugs, and pharmacists can use these inscriptions to support their assertions. If the composition written on the box is the same for the generic and original drugs, and if the State supervises the manufacturing of both drugs, this proves that the molecule at the core of both drugs is the same. Believing that both drugs are identical is simply believing in the capacity of the state to impose its authority on drug manufacturing. If patients don't believe in such a capacity, the inscription on the boxes of drugs is no more than an inscription... But most French patients have faith in this capacity, as long as there is no major accident with generic drugs in France. Some of the patients that we interviewed even believed that the state itself was producing the generic drugs. Confidence in the state seems to be strong in France.

Pharmacists could also use industrial arguments in defending the identity between generic and original drugs. To support this, some generic laboratories have passed license agreements with producers of original drugs, which gives them the opportunity to use the same supplier. In this case, only the box is different; the products are strictly identical. These drugs are often used by pharmacists as an example: pharmacists show patients the name of the factory on both boxes to convince patients of identity. Once the patient agrees with the fact that generic and original drugs are really identical in such a case, pharmacists can use the general notion of "generic drug" to shift from this particular case to other cases and assert that all generic drugs are identical to original drugs. They also explain that most generic laboratories are subsidiary companies of big laboratories or that the links between all these laboratories are strong. In this case, it's the industrial logic which helps the pharmacist: "If you trust the other laboratories, you have no real reason not to trust generic laboratories".

Pharmacists defend the identity of generic and original drugs with various traditional supports of trust: their ability as health professionals, the intervention of the state as a

⁷ Tablet, capsule and all the oral forms are considered as a same pharmaceutical form.

⁸ Agence Française de Sécurité Sanitaire des Produits de Santé. (French Agency for the Drug Security)

guarantor of public interest, or the proximity of laboratories in a production community. We have put forth the entire set of arguments at pharmacists' disposal, but, most of the time, the pharmacists' justification process does not go this far. They don't have the time to argue, and they don't always master all of these elements or think that the patients won't understand them. When patients argue, pharmacists simply stop arguing or propose that patients test the "new" drugs and, if they are not satisfied, change next time.

Nevertheless, whereas the inscriptions on the boxes and the word of the pharmacists guarantee that original and generic drugs are the same, patients can discover at first glance that there's a myriad of small dissimilarities between the two drugs. First, the name of the drug isn't the same. As we noted earlier, original drugs have a trademark name that has many connotations as to the desired effect of the drugs, whereas generic drugs are named with the ICD, which is sometimes quite difficult to memorize. The substitution of drugs is also a change of names which can lead to a dangerous state of confusion, especially with older persons who are used to taking the same drugs over a long period of time. The pharmacist often writes the name of the original drug on the box of the generic drug to facilitate transition, but the juxtaposition of the two names can also support the idea that both drugs are not really the same. There are other dissimilarities in the exteriors of the boxes and drugs, notably in their shape and colour. Generic laboratories can also legally use other excipients⁹, which they do in order to save money on manufacturing or to circumvent the licenses of other laboratories concerning colour, form or manufacturing processes. How can we speak of identical products if their appearance can vary so much?

For some patients, these dissimilarities in the external aspect of generic drugs can stir radical doubt about the quality of the drugs. These doubts are of two types. First, these minor differences can pose practical problems to patients and have important consequences in the observance of the prescription. As we said before, changes in colour, form or name may induce confusion, especially in older persons or in people who take many drugs. Pharmacists have reported cases of older persons with old boxes of the original drugs taking double dosages of the generic and original medicine together, thinking they're different drugs. There are also problems with the excipients, which may induce allergic reactions and are at the source of many debates between pharmacists and patients. Last but not least, there are problems with divisible drugs, because some generic drugs are difficult to divide and patients

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⁹ Excipients are elements lacking in therapeutic value which are added to the molecule to give a drug its form or colour or make it easier to integrate into the body. In very rare cases, they can have consequences on patients' health (eg. in case of allergy). They contribute to giving the drug its colour and external form, which can vary from original drug to generic drug.

may be tempted to take one half instead of one fourth, which may have serious consequences on their health.

Second, the patients can interpret these dissimilarities as the sign that laboratories are investing in the quality of the drugs. In that case, dissimilarities in the external aspect are understood as a sign of possible differences in the active molecule. This doubt doesn't only touch the composition of the drug but also the system of measurement which is established to guarantee the composition. What is interesting with this doubt is that it can become a self-fulfilling prophecy. When doubt is in place, the patient becomes attentive to the slightest differences in his bodily and psychic state. Doubts about the identity of the drugs become doubts about the identity of the effects of the drugs. Thus, pharmacists are often faced with patients who contest the effectiveness of generic drugs in their case.

Patients' remarks often leave pharmacists angry. They are torn between their faith in the essential identity between generic and original drugs and their attention to patients' doubt, which plays a *de facto* role in remedy effectiveness. They interpret these cases as the *nocebo* (negative *placebo*) effect, which is a translation of what sociologist call the "self-fulfilling prophecy": When patients believe the remedy won't work as well, it isn't as effective... Nevertheless, they can't really distinguish between these *nocebo*-like cases and cases where lower effectiveness was due to true differences in the generic drug's composition. To settle this question, they must reaffirm their belief in the infallibility of Science, State and Market against the "individual" testing that patients defend.

There are two ways of measuring identity (or difference) between generic and original drugs, which translate to two conceptions of how to evaluate treatment: on the one hand, we have an official measurement which stands on law and statistics, i.e. the two main systems of normalization and generalization of measurement; and on the other hand, we have an "individual" measurement which is based on the bodily experience of the patient. Before agreeing on what are the relevant differences between the two types of drugs, pharmacists and patients must agree on what is the right system of measurement, i.e. the right principle to which we should reduce the question. Price plays an interesting role in this decision.

"Why is it cheaper?" What does the price measure?

The generic drug is less expensive. Most French people today are conscious of that important difference which is constantly repeated by pharmacists and the media. But what does this difference mean? This problematic can be divided into two main questions: How

can we explain this difference of price between two identical products? Why should the patient pick the cheapest of the two drugs? In this part, we will see that these two questions, instead of separating measurements of the products' quality from price, set the price as en essential matter in the dynamic of qualification of the products. The price can be interpreted as a way to distinguish between both the products and the patients.

When pharmacists present generic drugs for the first time, they always say: "It's the same thing as the original drug but cheaper." This assertion seems logical to many actors in the field of health but can seem quite paradoxical to a novice. If products are really identical, why is one of them cheaper? To justify this difference of price, pharmacists generally explain that the laboratory producing the original drug had conducted research to discover it and, for that reason, had a license permitting it to be the sole producer of this drug. Now that the license is expired, other laboratories that did not invest in research can offer the drug at a lower price. Through this explanation, they imply that competition between laboratories and the end of license protection "automatically" creates lower prices and that the only cause of price difference is research cost.

This interpretation is contested, however, by some patients who transfer "reflexes" they acquired in other—especially food—markets where "generic products" already exist to their interpretation of the pharmaceuticals market. In these other markets, they claim that differences of price are partially explained by differences in quality, even if the "trademark effect" exists: "If it's cheaper, it's not so good." Some patients believe that the difference in price is linked to economies made on the manufacturing of the drug. This belief may be reinforced when they see dissimilarities in the external aspect of the two drugs. The difference in quality may nevertheless be accepted as long as the price difference is important and the implied products aren't symbolically invested. But what happens when the product is a drug? Some patients refuse any generic drugs due to their belief that they are of poor quality. It is notably the case regarding foreigners who come from southern countries (in Africa or Asia) and who are used to calling local drugs whose quality is all the more questionable, "generic drugs". It is also the case of people who are provided with complete Social Security without paying for it themselves¹¹ and who think they may be the victims of some sort of restriction / savings policy: "Sub-patients" may get "sub-drugs". Other patients do not reject generic drugs in block but choose accessory remedies to test generic drugs.

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¹⁰ In the French case, the difference in price isn't really the consequence of competition between laboratories, as the price are set by French authorities in agreement with the laboratories.

¹¹ I'm referring here to the *Couverture Maladie Universelle* (Universal Disease Protection), a complementary insurance provided by the state to people who cannot pay for one themselves.

The diagnosis of these patients is shared by some pharmacists and physicians who believe that the prices of generic drugs are too low to allow the laboratories to produce at a good level of quality and security. They fear that the competition between laboratories could lead some of them to cut costs on the manufacturing of generic drugs. Pharmacists are all the more conscious of this fact because they see the price they pay for these drugs, which is even lower than that paid by patients. ¹² If pharmacists benefit from competition between generic laboratories, they also fear that this game might lead to an accident and be dismantled.

To interpret the difference in price, actors are basically hypothesizing on the way that the drug market works: either the competition is seen as virtuous, in which case the difference in price is interpreted as being linked to the "trademark and license" effects, or the competition is perceived as potentially dangerous, and the difference of price is interpreted as a sign of quality differences.

But the difference in price isn't solely a way of comparing products. Even when the patient is convinced that generic and original drugs are the same, he may wonder what interest he has in choosing a generic drug. In other countries, such as the United States or the United Kingdom where generic drugs have been developing for years, the reasons behind the choice are quite simple: patients save a lot of money when they purchase generic drugs. In France, the problem is more complicated because the larger part of the cost of care is reimbursed by the Social Security and complementary insurances. Thus, the official Haut Comité pour l'avenir de l'Assurance Maladie (High Committee for the Future of Health Insurance) estimated the average rate of reimbursement at 78 % of the total cost. ¹³ Moreover, 91 % of French patients have a complementary insurance plan. Once reimbursed by the Social Security and his insurance, a French patient directly pays 80 € per year on average. This socialization of care expenses sets the classic problem of the "freerider" [Olson, 1965] in motion. Because it separates the individual contribution from the collective expenses, it complicates the evaluation of this contribution and can induce opportunist strategies. The fact that many patients ignore the price of their drugs may be explained by this logic of reimbursement as well as the organization of the pharmacy as we remarked in the first part.

But if the patients don't know (and don't care about) price differences, how can one explain the success of generic drugs¹⁴ whose only attraction is their price? In fact, there is a

¹² Pharmacists pay 40 to 50 % less than patients for generic drugs, and generic drugs are often 20 to 35 % cheaper for patients than original drugs.

¹³ Report of the Haut Comité pour l'Avenir de l'Assurance Maladie pp.34–47.

¹⁴ According to the *Caisse Nationale d'Assurance Maladie* (National Health Insurance Treasury), the rate of generic drugs in the list of genericable drugs was 60 % in 2005.

strong perception amongst many patients who take generic drugs that their choice represents a civic act. When I discussed generic drugs with patients, they referred to Social Security. They accept the idea of sweeping away their doubts and sacrificing their habits if it provides a way of salvaging the Social Security system. This civic role is easier to sustain when the patient is convinced that both drugs are the same. It can also be interpreted as a self-interested choice, as the patient benefits individually from the Social Security system. These same arguments are reversed by other patients who reject this logic of collective reimbursement. In their minds, the generics drugs are not a solution to the problems of Social Security, or they think that they don't benefit enough from the system. Another way of understanding the problem of price is related to laboratories. Some patients affirm that they take generic drugs in order to penalize big laboratories for their position on the Third World problems or their profits, which are judged to be exaggerated. Conversely, other patients—supported by their doctors—choose original drugs because they think that the profits made on the drugs will be reinvested into new research to create new drugs.

We see that the evaluation of price differences leads to more general and political questions since, through the choice of generic drugs, patients are positioning themselves in the debate on the future of health insurance and pharmaceutical research. The consumption of generic drugs can, thus, be characterized as an "ethical" choice since it involves more than a question of individual benefit. The notion of "psychological reward" developed by Max Weber [2003] to explain the relationship of the Protestants with their religion can help us to comprehend this civic posture. By choosing the generic drugs, patients have the feeling that they are directly acting on the Social Security deficit and, therefore, acting as good citizens. This "ethical reward" which emphasizes the ethical consequences of the decision, balances doubts about the quality of generic drugs but also diverts patients' attention from the concrete price difference between the drugs. The degree of price difference doesn't matter as long as it contributes to the fight against the Social Security deficit. This is another reason why French patients are indifferent to the prices of their drugs.

Similar to what we saw concerning the comparison of physical specifications of the original and generic drugs, here I want to defend the idea that the evaluation of prices implies more than a simple act of subtraction. First, the choice of generic drugs supposes the acceptance of the idea that price difference is solely the consequence of fair competition and not the sign of a difference in quality. This assumption cannot be taken for granted, notably due to the numerous dissimilarities in the external aspects of the drugs. Second, patients must decide if price difference is a sufficient motive for choosing generic drugs. In order to do so,

they must balance their self-interest and the collective interest. The choice between generic and original drugs is, then, an opening onto a range of more general questions about the functioning and future of the pharmaceuticals market.

Conclusion

If we consider the success of generic drugs in France from the point of view of a mainstream economist, the situation seems obvious: Assuming that the products are the same only less expensive, it would be irrational not to choose generic drugs over the original. This paper is intended to show that the calculations made by patients and pharmacists are much more complex. Choosing between original and generic drugs not only implies a capacity of calculation but also an agreement between actors about their understanding of the environment in which these drugs are created and sold. Measuring the differences between physical specifications of the generic drug and those of the original drug sets the drug as a care device, which involves a corporeal system of measurement, against the drug as a scientific object, which involves a scientific, legal and industrial system of measurement. Concerning the measuring of price differences, medicine as a collective investment - in Social Security and laboratory research, which implies a reciprocal gift system, is set against medicine as a commercial object, which opens us up to the domain of economic calculation. Under these circumstances, we can understand why what seems like such a simple object can leave some people so utterly perplexed.

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