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To Prescribe or Not to Prescribe

On the Regulation of Pharmaceuticals in Developing Countries

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A simple model is derived for determining which drugs should be available over-the-counter (and thus widely available even to those without access to formal health care) and which should be sold by prescription only (to reduce the dangers of errors in self-prescription).

This paper — a product of the Population, Health, and Nutrition Division, Population and Human Resources Department — was presented to the Second Congress on Health Economics in Zurich, Switzerland, in September 1990. It is part of a larger effort in PRE to determine methods for valuing information and information provision in the health sector. Copies are available free from the World Bank, 1818 H Street NW, Washington DC 20433. Please contact Otilia Nadora, room S6-065, extension 31091 (17 pages).

From a theoretical perspective, Hammer examines policy considerations in the choice between allowing drugs to be sold over-the-counter and allowing them to be sold only under prescriptions issued by health professionals.

The essential tradeoff can be stated starkly. On the one hand, people are likely to make potentially large errors in self-prescription, with serious consequences. On the other hand, limiting drug availability to those with access to formal health facilities will exclude many from the market or run the risk of making drugs prohibitively expensive.

Hammer sets out a simple formal model and discusses the types of drugs that are optimally handled in one mode or the other.

What factors determine this choice? The nature of the drug, the relative precision of professional diagnoses versus those of the public, and the demand characteristics of health care.

Hammer also examines the effects of different policy options such as pricing policy, the training of professional personnel, and essential drug lists.

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**To Prescribe or Not to Prescribe:
On the Regulation of Pharmaceuticals in Less Developed Countries**

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An important source of failure in markets and justification for government intervention in the health sector of LDCs is imperfect information. Pharmaceutical use is one area in which widespread problems have been noted (Lashman-Hall (1986), Foster (1990)) with substantial misuse, improper diagnosis and problems of compliance noted among both the population at large and health care providers, presumably due to a lack of information concerning appropriate use.

One possible instrument vis-a-vis the regulation of pharmaceuticals in LDC's (and in developed countries as well) is the decision by public health officials to make a particular drug available over the counter (OTC) to consumers or to require a prescription from a licensed professional. The choice is one of balancing two competing risks. On the one hand, allowing self-prescription by the consumers who do not have medical training runs the risk of gross errors of diagnosis and mistaken prescriptions with possibly serious health consequences. On the other hand, requiring the intervention of a skilled professional incurs the risk that the patient does not receive the appropriate, potentially life saving, drug at all. With medical personnel in very short supply in many parts of the developing world, the real cost (including travel time and expense) of visiting licensed medical facilities can be prohibitively high. This paper presents a very general methodology for evaluating the tradeoff between these competing risks. The problem can be considered one of determining the value of information (in the form of a more accurate diagnosis through the intervention of a skilled professional) as a particular (and costly) mechanism for obtaining this information.

The model presented here identifies the information needed to answer the question concerning this regulatory issue with illustrative examples. Further, the model provides some guidance in related issues for the determination of an appropriate level of training to be required for professionals and the evaluation of projects to improve public access to information on the use of drugs.

Statement of the Problem -

For a first, very simple, approach to this problem let us assume that the appropriate drug for a given condition is known and that the only uncertainty that a person who is sick faces is in the correct dosage, both per application and in a full course of treatment. The policy choice is whether to make the drug available over the counter or to require a prescription by a licensed professional. In the former case, the patient is left to his or her own devices as far as determining the correct dosage. This choice is subject to considerable error. The outcome of the choice is evaluated with respect to a loss function $L(d;D)$ which gives the consequences of choosing dosage d given that the "correct" choice is D . In the most general form, the function $L(\cdot)$ includes technical factors which involve not only the medical consequences of the choice but can also include the consideration of personal judgments of discomfort, price and so forth which may make the "optimal" choice from a patients' perspective differ from that of a licensed practitioner. For the time being, this distinction is ignored and the loss function is the objective cost of making an error in dosage.

The error $\epsilon = d - D$ is characterized by a distribution function $F(\epsilon)$ defined over a range $[\epsilon_1, \epsilon_2]$. This range reflects heterogeneity in the population. Not everyone gets the same dose and it is this uncertainty over patient-specific requirements which makes the problem nondegenerate. The function $F(\epsilon)$ is quite general in that it can reflect biased judgments leading to systematically excessive or insufficient dosages. That is, the mean error need not be equal to zero. Making one more assumption that the loss is dependent on the arithmetic error of dosage, the loss function can be rewritten as $L(\epsilon)$ in terms of the error alone. Given these components, the expected loss due to self prescription (with expectation taken over the population which potentially needs the drug) is:

$$\int_{\epsilon_1}^{\epsilon_2} L(\epsilon) dF(\epsilon) \quad (1)$$

In the case of prescription, there are two modifications. On the one hand, if the patient seeks medical care, the assumption is that the error involved in the determination of the dosage is smaller than it would be in the case of self-prescription. If this is not true, then there is no point at all in requiring prescription. The difference in the distribution function can reflect the reduction of bias involved in self prescription or it can be a result of a reduction in the variance of prescription around the correct value. The errors made by the professional are characterized by a distribution function $G(\epsilon)$. The expected loss, conditional on someone obtaining the improved information from the professional is:

$$\int L(\epsilon) dG(\epsilon) \quad (2)$$

which is less than the loss entailed in equation (1). The limits of integration are left the same with an assumption that the range of error with professional help is no larger than with self prescription, although this is inconsequential since the limits can be arbitrarily wide.

On the other hand, by making the drug available only by prescription, it is possible that some fraction of those who need the drug will not be able (or will choose not) to obtain the drug. By requiring the intermediary, the cost of obtaining the drug has increased, perhaps dramatically, since the cost of visiting the professional is an added cost to the drug itself. Even if professional help is available free of charge at public clinics, the cost of time and travel to the clinic may be prohibitively expensive for some people, particularly those in rural areas. The problem of choosing to seek health care, in this case as a function of these costs, should be related to the perceived value of the prescription and hence to the loss function specified above. However, given that the decision is made under severely constrained information, the link between willingness to pay and welfare as captured in the function L is problematic. For the time being, let P represent the fraction who choose to seek health care and a prescription without using this term as indicative of the value of L . Given a particular disease and a constant set of price and cost parameters,

we can then assume that P can be determined independently of the other variables in the problem. Therefore, the fraction $1-P$ of the population does not receive the drug and suffers the loss L_0 . The overall expected loss in the case with required prescriptions is:

$$(1-P)L_0 + P \int L(\epsilon) dG(\epsilon) \quad (3)$$

It is no longer clear that this loss is smaller than that incurred in (1). L_0 is presumably higher than the expected loss due to self prescription. If this is not true, the problem is trivial in that self prescription is then worse than no access at all and should never be allowed. Therefore, the problem is simply to compare the values of the expected losses in equations 1 and 3 and to follow the regime with the lower cost, given the functions $F(\epsilon)$, $G(\epsilon)$ and $L(\epsilon)$, the pattern of errors made by unaided consumers, and professionals and the related function indicating the cost of these errors, respectively.

In a practical application, the relevant information could come from a variety of methods which have been developed to look at the separate components of this problem. As for the specification of the loss function, much might be transferred from the literature on utility levels associated with different health states (see Torrance (1986) or Torrance et. al. (1982) and references therein).

While not addressed to the effects of dosages of drugs this literature may be useful in tying one's physical condition to mistakes in drug prescription. Making the link between degrees of debility from misuse and the categories used in assessing health should not be nearly as difficult as determining the various utility levels of physical conditions in the first place. Modifications of these scales to incorporate utility from money (incorporating the different valuations of patient and prescriber) may be arbitrary but can be used in a sensitivity analysis when numerical calculations need to be made.

As for the distribution of errors in drug use, there have been a number of studies made to assess the prescribing behavior of doctors in developed countries (see). With some refinement, it should be possible to assign probability densities for varying types of errors. If the categories for the

assignment of error are the same as these used in the appraisal of utility, the calculations can be made numerically without having to find explicit functions for either $L(\epsilon)$ or $G(\epsilon)$. Patterns of self prescription necessary for identifying the function $F(\epsilon)$ have been studied in a number of contexts (see van der Geest (1987) and references therein and Greenhalgh (1987)) and would have to be done in individual contexts.

Illustrative Case

The above formulation can be made more specific by choosing these functions and solving analytically for the two cases. Most realistic loss functions will tend to be too difficult to solve analytically and the example here is chosen only for its convenience (and, not coincidentally, for the fact that it is the common convention for problems of this sort). Let the function $L(\epsilon)$ be equal to $a\epsilon^2$ for values of ϵ in the range $[\epsilon_1, \epsilon_2]$ and equal to the known constant L_0 for $d=0$ (that is, with $\epsilon = -D$). This is essentially a quadratic loss function for some neighborhood of the correct diagnosis with the minor modification that the loss, when no drug is taken, can be specified independently. Otherwise it would be constrained to equal $a(-D)^2$. This merely helps alleviate some of the strong assumptions implicit in this functional form when extended over a large range. It will be argued below that this form captures several of the most interesting features from the more general problem. With a quadratic loss function, the specification of the functions $F(\epsilon)$ and $G(\epsilon)$ becomes less critical since only the first two moments will matter. The only assumption concerning these functions is that the mean squared error around the true dosage be smaller for $G(\epsilon)$ than for $F(\epsilon)$.

With these substitutions, the solution to the special case is reduced to the choice to sell over the counter rather than by prescription if and only if:

$$(1-P)L_0 + P \int a\epsilon^2 dG(\epsilon) > \int a\epsilon^2 dF(\epsilon)$$

or:

$$(1-P)L_0 + Pa(\sigma_T^2 + b_T^2) > a(\sigma_o^2 + b_o^2) \quad (4)$$

where σ_i^2 = variance of errors around the correct dosage made by i^{th} person = (T for trained professional, O for OTC purchases)

b_i^2 = squared bias of errors around the correct dosage made by i^{th} person

The choice, therefore, depends on the mean squared error ($=\sigma_i^2 + b_i^2$) of the two decision makers.

We can define the relative advantage of selling OTC as:

$$R = (1-P)L_o + Pa(\sigma_T^2 + b_T^2) - a(\sigma_o^2 + b_o^2) \quad (5)$$

Using this, we can draw a number of conclusions. First, OTC is more likely to be the preferred policy to the extent that (1) the consequences of complete non-availability of the drug (L_o) is large, (2) the gain in precision of the correct dosage ($\sigma_o^2 - \sigma_T^2$) is small, (3) the bias involved in self diagnosis is small ($b_o^2 - b_T^2$), (4) the severity of mis-diagnosis is small, and (5) the proportion of people denied access to the drug ($1-P$) is large (assuming, of course, that L_o , the loss incurred by not having the drug is greater than $a(\sigma_o^2 + b_o^2)$, the expected loss of treatment by a professional). These are all quite intuitive. The advantage of having a professional intervene in the choice of drugs is dependent on the value of the information he or she can provide. This is dependent on the increased precision in identifying the correct dose (σ and b), and the consequences of error which are captured by the parameter a , or how fast losses accrue as errors increase. These must be balanced against the consequences of closing a proportion of the population out of the market. This in turn depends on the parameters P and L_o .

The above results can provide insight into what kinds of drugs might fall into either category. The following diagrams illustrate a few of the different possible forms for the loss functions and their implications. The choice of the quadratic loss function is quite restrictive in many ways (the implicit symmetry of effects of over- and under- treating the disease is the most obvious). In each of the diagrams, a "realistic" form of the loss function is given in addition to a representation by the quadratic case with the free parameter L_0 . The diagrams are inverted so that the "optimal" dosage appears as yielding the maximum benefit (equivalent to the minimum loss).

Figure 1 presents the circumstances in which selling the drug OTC is most likely to be preferred. In this case, being denied access to the drug is very costly as evidenced by the value of the benefit function at zero. Further, the function is relatively flat in the neighborhood of the optimal dose. This will accompany a low value of the parameter "a" in the quadratic case. In the general case, the point is that errors incurred in overdose are not very serious. Even with this loss function it is possible that prescriptions are preferable depending on the relative pattern of errors which the public or professionals are likely to make. If professionals are highly accurate, this might counter the characteristics of the function $L(\epsilon)$. But for a given structure of knowledge, this form would dictate the use of OTC. The best example of a drug falling into this category would be the use of chloroquine in areas endemic with malaria which also have immigration by people who are not immune to the disease. In these areas, the consequences of limited access to the drug would be high mortality rates, as people with low immunity enter malarious zones (Najera et.al. (1990)), and low risks of over dose. Were it not for the encouragement of resistance in the parasites, this conclusion would be just as strong in any malarious area, although it is likely that chloroquine would always be better sold as an OTC, as it generally is in the LDCs. The possibility of a social cost from resistance is discussed below.

Figure 2a shows the clearest case for requiring a drug to be sold by prescription. In this case, the consequences of not having the drug at all are small (the intercept - L_0 is at a high level) while small

FIGURE 1
OTC Preferred

FIGURE 2a

Prescription Preferred

FIGURE 2b
Prescription Preferred

FIGURE 3
Ambiguous Result

errors around the optimal dose are significant, or at least, the consequence of overdose are serious. In this case, the quadratic approximation of the true cost goes somewhat awry since it is constrained to be symmetric around the optimal dose. In practice, this can be corrected by choosing a relevant range of errors which extends further to the right of the optimum; however, this compounds the effects of the error structure and the costs of these errors. Examples for this case are a bit contrived but might include codeine based cough medicines which can have addictive properties with over or extended use. More common might be the case illustrated in Figure 2b, where not only are errors of overdose serious but those of underuse are serious as well. Examples of this case might include antibiotics for self-limiting conditions. In this case, lack of the drug is not dangerous although it will prolong the length of time a person is ill. On the other hand, errors near the optimal dosage can be serious in both directions. Underuse of the drug may lead to the development of resistance and is a source of an externality imposed by one consumer on others. Overuse can also be harmful. While the discussion thus far has emphasized the loss function defined for an individual user, these external effects can easily be accommodated. Note that with higher costs associated with underuse of the drug, the quadratic approximation performs better in case 2b than it did in 2a.

Figures 1 and 2 show cases in which the choice between the two regulatory options is clear. Figure 3 shows the case where precise information on the parameters of the problem would be necessary to reach a conclusion on the issue. Here, both dimensions of the trade-off pose serious problems. The failure to obtain the drug at all has serious consequences but the risk of misuse is large as well. One example might be insulin. It is in cases such as this that the value of an explicit framework for evaluating the relative risks is greatest. Note that, as pictured here, a quadratic characterization is fairly accurate.

Clarifications and Extensions

The loss function, as defined above, serves to motivate the simple argument made this far. However, there are a few issues related to its characterization which could use some elaboration. In an

examination of the relative merits of using OTC versus prescription for three drugs in the U.S. context, Temin (1983) identified two very different criteria for assessing the effects of public policy on welfare. The first was based on the willingness to pay or on the observable demand functions of consumers. In most contexts, consumer choice is a good indicator of personal preferences and the utility derived from these choices. These are generally an appropriate basis for deriving social welfare. However, given the level of ignorance of most consumers about the various medical options available and their consequences, a second criteria might be the actual physiological outcomes to be expected from the drug without reference to the demand curve.

In the model presented here, the loss function is to be considered as a hybrid between personal preferences and an "objective" appraisal from a medical perspective. On the one hand, losses are assumed to be lower the closer one gets to the medically "optimum" point. On the other hand, the loss function described here should take into account personal preferences over discomfort and costs which may not enter into a purely medical judgement. In a sense, the ideal loss function for an individual is the one which would be induced by private demand under circumstances of complete information on the part of that individual. This would correctly balance the consumers preferences for health versus the other uses of resources. Deviations from this optimum which the consumer is likely to make are largely due to ignorance. In the characterization above we would then expect the term σ_o^2 to be large (relative to b_o) and to reflect this ignorance of medical outcomes. In the case of professionals, the components of the error might be due in part to the ignorance of medical consequences (Barnett, Creese and Ayivor (1980), Hanlon (1983)) but will also include errors in the agency role of reflecting individual wishes. There might also be a systematic bias induced from a tendency to underplay the role of price or non-medical considerations in the choice, so that b_T may be significant. Indeed, if the provider sells the drugs, there may be more than innocent mistakes involved in this bias (Lashman Hall (1986)). The role that individual choice, as reflected in demand functions, plays in this analysis is relegated only to the determination of P , the probability of seeking professional help. Therefore, while implicit in the evaluation function, demand appears explicitly

only as a constraint on the choice of provider as seen from the policymakers' perspective.

Finally, there is little to complicate the aggregation of these functions to market level except in the case of inducing resistance against drugs. This might be handled very simply as was done in Figure 2b, though the problem of resistance inducement is complex and in need of further analyses which combine epidemiological and economic reasoning. One possible policy which might be derivable from the above analysis might be to prefer prescriptions as a means of delivery with a subsidy to the pharmaceutical itself. In this case one might have a bias induced toward low compliance (due to the actual cost of drugs or to a tendency to stop treatment if a condition improves, or both) which the subsidy might be partially effective in countering. Generally speaking, identifiable sources of bias may be countered by appropriate taxes or subsidies, particularly for self prescription.

One extension of the simple model is to allow for more complicated loss functions than quadratic. The most natural extension is to maintain a polynomial loss function but increase the degree of the polynomial. For every extra term included in the polynomial approximation, one more moment of the distribution function of the error terms in $G(\epsilon)$ and $F(\epsilon)$ needs to be specified. So, if the loss function can be written $L(\epsilon) = \sum d_i \epsilon^i$ then

$$\int L(\epsilon) dF(\epsilon) = \sum d_i \int \epsilon^i dF(\epsilon) = \sum d_i M_i(\epsilon; F(\epsilon))$$

where d_i 's are the coefficients of the polynomial expansion of $L(\epsilon)$ and $M_i(\epsilon; F)$ is the i^{th} moment of the distribution function $F(\epsilon)$. This simply adds more terms to equation 4.

A more important extension would be to the case of multiple drugs. In a purely formal sense, the above framework could be modified to take into account the joint problems of many drugs. One would need to account for cross drug effects where the probability of seeking care may be a function of the range

of drugs available OTC, even those not necessarily appropriate for the condition being considered. A full description of the problems encountered when dealing jointly with substitutable drugs (whether truly substitutable or not (Foster (1990))) is beyond the scope of this paper.

Finally, this approach can be used to examine some related issues on information provision. Equation 4 is familiar as a modification of the value of information in a quadratic loss context (Arrow (1971)). A prescription for a drug is a type of information or variance reducing procedure. In the above framework, two questions related to the prescription question can be raised. First, what levels of training should be required for prescriptions of different types and second, what is the value of information, education and communication (IEC) programs directed at consumers themselves. In either case, the policy to be examined is the release of a message (I) through relevant channels. For professionals, this might be embodied in formal training or for messages specifically directed towards them. For consumers, the channels for IEC messages might be media announcements, brochures, etc. In either case, the terms σ_i^2 and b_i can be considered functions of the message (I). Associated with these messages are costs $C(I)$. In order to choose an appropriate level of training for a prescriber, once the decision to make a drug available by prescription only has been made, we can compare marginal benefits from improved messages

$-Pa \left(\frac{\delta \sigma_T^2}{\delta I} + \frac{\delta b_T^2}{\delta I} \right)$ with the marginal costs $C'(I)$. The former term is certainly decreasing in I since there will be no benefit after "perfect" prescriptions are attained, the latter certainly rises. Therefore, there will be some optimum level of training to require of prescribers or information which should be provided to prescribers. Note that in the case of finding the level of training, the benefits must be the net effects of improved prescribing behavior over the subsequent career.

For the consumer, the same analysis holds with the marginal benefits being

$$-a \left(\frac{\delta \sigma_o^2}{\delta I} + \frac{\delta b_o^2}{\delta I} \right)$$

channels for IEC messages might be media announcements, brochures, etc. In either case, the terms

_____. Note that there is no discount for P - the proportion seeking help. A joint decision between requiring prescriptions and choosing the appropriate recipients of information can be made on these grounds. The precision of prescriptions may be increased more easily for already trained professionals but will be more useful to the extent that people rely on professional help. The extent to which professional versus consumer decision making can be improved by information and education campaigns will also affect the joint decision of whether or not to make the drug OTC and to whom the campaign should be addressed. This type of reasoning can apply to any IEC type of intervention. Other interventions may also have effects through error reduction. In particular, this framework might be used to quantify the benefits of essential drug lists. It is precisely through the reduction in prescription and consumer error that the simplification of choices induced by the essential drugs lists will operate (beyond reduction in procurement costs).

This paper has examined a simple model for determining the appropriate form in which a pharmaceutical should be delivered. The relevant analytic concept was seen to be the value of information. Given the widespread ignorance on the part of consumer and providers of health care in less developed countries, this sort of analysis may have wider applications to the analysis of other health policies as well.

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