Drug Licenses: A New Model For Pharmaceutical Pricing

Drug licensing fees for patients could benefit the patients themselves, their health plans, and the drug manufacturers.

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ABSTRACT: High drug prices are a major barrier to patients' access to drugs and compliance with treatment. Yet low drug prices are often argued to provide inadequate incentives for innovation. We propose a drug-licensing model for health care, which has the promise of increasing drug use without altering patients' out-of-pocket spending, health plans' costs, or drug companies' profits. In such a model, people would purchase annual drug licenses that would guarantee unfettered access to a clinically optimal number of prescriptions over the course of a year. Using the example of statins, we illustrate how such a model could be implemented. [*Health Affairs* 27, no. 1 (2008): 122–129; 10.1377/hlthaff.27.1.122]

SPENDING ON PHARMACEUTICALS IS OUTPACING growth in total spending on health care in the United States and in many other Westernized countries. In the United States alone, drug spending grew 10 percent from 1998 to 2003, compared to 5 percent for health care overall.[1] Despite its modest contribution to overall health care spending, increased drug spending has raised concerns about increasing costs in health care more generally and the impact that high prices could have on access to much-needed pharmaceutical products.

For clinicians, the most important consequence of this trend may be the dramatic increase in patients' out-of-pocket spending and how this affects patients' behavior and health outcomes. Physicians, out of concern for patients' compliance with and access to treatment, regularly encourage behavior designed to mitigate high prices. For example, physicians often distribute free samples to patients with financial need.[2] Also, pill splitting—the act of dividing higher-dose tablets to avoid expensive copayments—is commonplace. These practices are not limited to patients and physicians; the Illinois Medicaid program now requires pill splitting for some drugs, and UnitedHealthcare in Arizona recently began requesting that its beneficiaries engage in the practice as well. But pill splitting entails risks and is not possible for all drugs.

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The fundamental clinical problem is that high prices are a barrier to patients' compliance with treatment. In a *Wall Street Journal*/Harris Interactive poll, 35 percent of adults cited financial considerations as a reason for noncompliance.[3] These results are corroborated by numerous studies.[4] The impact of high prices on patients' compliance is important because poor compliance can lead to worse health outcomes through uncontrolled hypertension, high cholesterol, untreated psychiatric illness, and resistant bacterial infections, to name a few. Noncompliance can also reduce productivity and greatly increase medical costs.[5]

What Can Be Done?

■ **Lower drug prices?** The solution to high copays and prices most discussed is to mandate lower drug prices—for example, by allowing reimportation of drugs from Canada or other countries or by requiring Medicare to negotiate drug prices. But there are two enormous obstacles to regulating prices in this way. The first is that lowering prices can defeat the purpose of the patent system and can reduce incentives for future pharmaceutical research and development (R&D). Although some prominent critics have rightfully questioned the link between profits and R&D, the absence of R&D into unprofitable third-world diseases and the increase in R&D for certain rare diseases after the U.S. Orphan Drug Acts suggest otherwise.[6] Moreover, the (limited) economic evidence suggests that price regulation can delay the launch of new drugs, limit the availability of new drugs, and reduce the pace of innovation.[7] Critics contend that this link is tenuous and that the status quo may offer too much incentive for R&D, especially "me-too" innovation. These concerns are particularly relevant to health care, where the existence of health insurance may encourage too much costly innovation.[8] Nonetheless, whatever view one may take, the reality is that the drug industry vigorously opposes lower prices, which might make such prices politically difficult to implement.

■ **An alternative: drug licensing.** We propose an alternative approach to drug pricing that has the potential to improve patients' compliance without lowering profits to pharmaceutical firms and insurers. In this model, all patients would pay an annual "licensing fee" for the drugs they take; in return, they could purchase medication with nominal or nonexistent copayments up to some therapeutically optimal level—for example, twelve monthly prescriptions per year. Pharmaceutical firms would charge health insurers a license fee for each patient receiving unfettered access to their product(s), up to the predetermined level. In return, pharmaceutical firms would sell their drugs to the plan at very low cost, rather than at the typical mark-ups that characterize patent-protected, brand-name medications. To prevent resale, the number of units dispensed to the insurer would be bounded by the number of licenses sold multiplied by the maximum number of prescriptions allowed per license. The health plan would then pass this cost structure on to its beneficiaries in the form of a separate but similar drug license with low or nonexistent copayments—in effect, patients would purchase drug licenses from insurers, and

insurers would purchase drug licenses from manufacturers.

Such a model would apply to any disease for which repeated medications are required for effective treatment and in which treatment costs depend on the level of use. This would, of course, be true for chronic diseases such as asthma and diabetes, for which medications are taken over a long period and prescriptions are financed, say, monthly. Drug licensing would also apply, however, to slightly more acute diseases in which prescriptions must still be filled and financed monthly—for example, a nine-month antibiotic treatment for tuberculosis.

The licensing model we propose is referred to by economists as "two-part pricing." Numerous examples of this exist in the nonmedical world, including Internet service, cable and satellite television, all-you-can-eat buffets, country club memberships, and cell phone plans. But perhaps the most relevant example is software. Instead of charging a fee every time a person starts his or her computer, Microsoft charges a one-time fee for the use of Windows. What makes pharmaceuticals similar to these products—and distinguishes them from other health services—are the very low costs of production and the existence of few good substitutes.

In each of these instances, consumers pay a fixed fee up front, after which they pay a very low (or nonexistent) amount for use of the good or service. Because usage fees are lower than they would be if charged per unit (the manufacturer makes up for this cost with the license fee), those purchasing the product end up using more of it than they would if marginal prices were higher. For example, in the case of pharmaceuticals, license fees combined with zero or low copays would increase drug use (that is, compliance) in the same way that buffets induce people to eat more and free music-sharing programs induce them to download more (Napster versus iTunes). And because increased utilization is beneficial to patients (at least in the case of pharmaceuticals), patients, health plans, and manufacturers can share some of the added value generated by the licensing model.

An Illustrative Example: The Case Of Statins

To demonstrate how patients' compliance can be improved while leaving health plans' costs and drug companies' profits unchanged, we consider the illustrative example of drug licensing for statins, for which ample empirical evidence exists that copayments have a large effect on compliance. Defining *compliance* as the proportion of prescribed days for which prescriptions are filled, Dana Goldman and colleagues estimated the relationship between average copayments and average statin compliance for eighty-eight private health plans.[9] For each $10 increase in copay, statin compliance fell on average five to six percentage points. This estimate is conservative; Jennifer Schultz and colleagues found even larger effects.[10] Moreover, for a monthly copay of $25—the average copay in 2005 in these same data—average compliance was only 65 percent. Based on these studies, a reduction in copayment from $25 to zero would improve compliance to nearly 80 percent, the threshold argued for statins to have therapeutically optimal effects.[11]

Based on these studies, Exhibit 1 provides a realistic illustration of how a properly designed license model for statins could improve patients' compliance while maintaining the status quo in out-of-pocket spending, health plans' costs, and pharmaceutical revenues. We consider a health plan with 10,000 beneficiaries, 1,000 of whom likely would be taking brand-name statin medications. We consider three scenarios: (1) a pure copayment model (the status quo), (2) a drug-licensing model with zero copayment and license fees paid by both the health plan and the statin user, and (3) a mixed model in which a license fee is paid in return for lower, but not zero, copayments. In the second and third instances, the drug license would allow up to twelve monthly prescriptions per license.

■ **Average statin compliance and copays.** Based on the literature, statin compliance averages 7.8 months at the mean copayment of $25, as opposed to 9.6 months when the copayment is reduced to zero. In the pure copayment model, annual out-

EXHIBIT 1
Benefits Of Drug Licensing To Patients, Health Plans, And Manufacturers: The Case Of Statins

	Status quo (copays)	Drug license	License and copay model
Number of covered lives	10,000	10,000	10,000
Prevalence of statin use	10%	10%	10%
Number of statin users	1,000	1,000	1,000
Patients (per statin user)			
Copay per prescription	$25	–[a]	$11
Cost-share on the license	–[a]	$195	$95
Average compliance[b]	65%	80%	73%
Number of 30-day prescriptions annually	7.80	9.60	8.75
Out-of-pocket payment for statins[c]	$195	$195	$195
Health plan			
Plan prescription costs[d]	$374,400	–[a]	$374,400
Plan license costs[e]	–[a]	$374,400	0
Total cost for statins	374,400	374,400	374,400
Manufacturer			
Manufacturer price per prescription[f]	$73	$0	$54
Manufacturing cost per prescription[g]	0	0	0
Drug license fee	–[a]	569	95
Manufacturer profits	569,400	569,400	569,400

SOURCE: Authors' calculations.

[a] Not applicable.

[b] Based on compliance rates reported in D.P. Goldman, G.F. Joyce, and P. Karaca-Mandic, "Varying Pharmacy Benefits with Clinical Status: The Case of Cholesterol-Lowering Therapy," *American Journal of Managed Care* 12, no. 1 (2006): 21–28.

[c] Excludes premiums for statin coverage; in these examples, premiums would not change because plan costs are the same across scenarios.

[d] The number of statin users times the number of prescriptions annually times the price (net of copays).

[e] License fee net of patient cost sharing on the license.

[f] Based on average amount paid for brand-name statins (per thirty-day equivalent) by eighty-eight private health plans in 2004 exclusive of rebates.

[g] Assumed minimal for convenience.

of-pocket payments for statin users would therefore average $195 (7.8 prescriptions × $25 copayment). In the license example, statin users pay this amount up front as a license fee, and the copayment is eliminated. Compliance would improve to 9.6 months. Total out-of-pocket payments for statins would therefore remain the same in the license model, but average compliance would improve nearly 25 percent.

■ **License fees.** It is straightforward to show that for a correctly chosen drug license fee, both the costs to the health plan and the profits to the drug manufacturer can remain unchanged. We start with the status quo in which the drug manufacturer charges the health plan a price for each prescription that exceeds the cost of production, even with rebates. In the eighty-eight health plans we studied, the average amount paid by private health plans for brand-name statins was $73 per thirty-day equivalent. Some of this amount is paid by statin patients in the form of copayments; the remainder is paid by the health plan and is financed through normal premiums charged to both statin users and nonusers. In our example, the health plan's total statin prescription costs are $374,400; this is simply the average number of prescriptions filled (1,000 users × 7.8 prescriptions per user × $48 net price paid by the health plan).

In the pure drug licensing model, health plans would be charged a license fee ($569) for each statin user, to be paid to the manufacturer. This fee would give the health plan the right to twelve prescriptions annually at zero cost for each license. Part of this fee would be financed by a separate drug license sold to statin users ($195, similar to their out-of-pocket costs under the status quo), while the remainder would be paid by the health plan ($374). Since the net cost to the health plan is $374 per statin user, the total prescription plan costs would be the same as in the status quo ($374,400).

■ **Manufacturers' profits.** A similar analysis can be applied to the drug manufacturer. Under the status quo, the total profits from sales to the health plan are $569,400—this is equal to the price charged by the manufacturer net of costs ($73 per prescription) times the number of prescriptions filled annually (when the copay is $25) times the number of statin users. Under a licensing model, the health plan simply pays an up-front fee of $569 per statin user, which leaves the manufacturer's profits unchanged compared to the status quo.

■ **Welfare gains for all parties.** This example demonstrates that with a properly chosen drug licensing fee, patients' compliance can be greatly improved at no additional cost to patients or health plans and no change in profits to manufacturers. And although the recent introduction of generic Zocor (simvastatin) makes an illustration with statins less forceful today than two years ago, top-selling Lipitor still remains on patent and makes the basic conclusions of our illustration still salient. To the extent that patients value the health benefits associated with improved compliance or health plans experience cost savings as a result of reduced medical spending from better compliance, or both, plans and manufacturers can share in these welfare gains so that all parties can be better off with drug licensing.

Putting The Model In Place

■ **Infrastructure.** The infrastructure for such a licensing model already exists in health care. Insurance itself closely resembles a two-part pricing arrangement between insurers and patients—patients pay a fixed amount up front (through premiums) for the right to purchase health care services at lower cost. Our proposal is tantamount to designing a plan with very low copayments, with one important difference. Today, if an insurer offered a plan that covered chronic medications for essentially zero copayments, then the plan would need to worry about attracting the sickest patients. In fact, it is likely that concerns about risk selection have been at least partially responsible for the recent increase in out-of-pocket payments. In our model, the insurer pays the same amount regardless of utilization, so it has less incentive to avoid patients who use more therapy.

■ **Possible limitations.** It is worthwhile to consider some possible limitations of and objections to the licensing model. First, drug licensing will not eliminate the need for health plans to correctly identify those patients who should receive a given therapy. For example, patients whose clinical diagnoses do not warrant a specific treatment will not be offered the opportunity to purchase a drug license. Rather, for those patients for whom coverage is appropriate, drug licenses can ensure therapeutically optimal utilization without increasing out-of-pocket spending. Drug licenses can help those who stand to benefit from a drug to actually benefit from it. In this sense, drug licenses may complement other measures proposed to improve efficiency in utilization—for example, Value-Based Insurance Design (VBID)—by identifying patients who are most likely to benefit from a drug and offering them unfettered access at a fixed price.[12]

Second, while compliance will surely improve for those taking the licensed drug, it is possible some patients may be discouraged from initiating therapy if the license fee is set too high. We propose three solutions to this problem. The first is to implement a mixed model in which patients pay a lower drug license fee in return for lower copayments than the status quo. We illustrate this in the third column of Exhibit 1. With a copayment of $11, we estimate that patients initiating statin therapy will have an average compliance of 8.75 months. If patients pay a license fee of $95 (slightly less than the copayment for a four-month supply under the status quo), their total out-of-pocket spending is unchanged ($195), and compliance is still improved relative to the status quo. In this case, costs to the health plan and profits to the drug manufacturer are unchanged as well.

The second solution is to offer "nonresponse insurance" for patients who discontinue statin use within a given period of time. For example, those patients who discontinue use within three months of initiating therapy may be eligible for a partial or full refund of the license fee. Since profits to manufacturers and health plans are likely to be higher under drug licensing and the vast majority of statin sales are likely attributable to patients who use these drugs for more than three months, such a money-back guarantee may face little opposition by drug manufacturers

and health plans. In fact, such insurance is likely a good idea even outside of a licensing model. The third solution, for those who would otherwise use the drug but cannot afford the upfront license fee, is to offer a "drug loan." In this case, instead of paying the license fee up front, patients would pay in monthly installments until the license fee is fully paid.

Another concern with a licensing model is that minimal copayments could encourage excessive and inappropriate drug use—in economic terms, licenses could induce "moral hazard." Indeed, the impetus behind many "consumer-driven" approaches to health care is to require more prudent spending through health savings accounts and high-deductible health plans. However, closer inspection reveals that this criticism is irrelevant to the license model. First, increased use of prescription drugs need not come at additional cost to health plans, even when such use has no effect on lowering costs elsewhere in the health plan. Our example demonstrates that total plan costs for prescription drugs under drug licensing may be equivalent to—or even lower than—plan costs under copayments. Second, while copayments deter excessive drug use, they also deter appropriate use. Because appropriate use lowers the likelihood of expensive hospitalizations, health plans may benefit from reductions in medical costs as well. In fact, the empirical evidence on statins suggests that the reductions in medical costs due to lower copayments can be substantial.

The drug license model could also reduce manufacturers' incentives to aggressively market drugs to patients on therapy. The recent Food and Drug Administration (FDA) "black box" warning about the potential overuse of erythropoietin to treat anemia is a salient example. Under a licensing model, profits are tied to the number of patient licenses rather than prescriptions filled, so manufacturers have fewer incentives to encourage too much use. Rather, marketing efforts would be directed toward people who have not yet initiated therapy (as they are now).

Drug licenses also preserve incentives to advance medicine. Recent research has demonstrated that drug therapy generates enormous social value. This suggests the importance of a pricing mechanism that (1) reduces the cost of compliance and ensures benefits from these medical advancements, and (2) preserves manufacturers' incentives to develop new technologies. We believe that there is a strong basis for changing the current pricing structure for pharmaceuticals to the licensing model that we propose, thereby ensuring patients' compliance with drug therapy without potentially compromising the supply of future drugs. We urge pharmaceutical companies, Medicare, and private health plans—along with other parties responsible for purchasing or selling pharmaceuticals, such as employers and pharmacy benefits managers—to explore the possibilities of drug licensing. We believe that a pilot study of drug licensing that involves agreement between health insurers and manufacturers would be a useful way to examine and demonstrate the benefits of this model.

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NOTES

1. Organization for Economic Cooperation and Development, *OECD Health Data 2005: A Comparative Analysis of Thirty Countries* (Paris: OECD, 2005).
2. C.W. Tseng et al., "Cost-Lowering Strategies Used by Medicare Beneficiaries Who Exceed Drug Benefit Caps and Have a Gap in Drug Coverage," *Journal of the American Medical Association* 292, no. 8 (2004): 952–960.
3. Harris Interactive, "Prescription Drug Compliance a Significant Challenge for Many Patients, According to New National Survey," 29 March 2005, http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=904 (accessed 16 September 2007).
4. See, for example, D.P. Goldman et al., "Pharmacy Benefits and the Use of Drugs by the Chronically Ill," *Journal of the American Medical Association* 291, no. 19 (2004): 2344–2350; G.F. Joyce et al., "Employer Drug Benefit Plans and Spending on Prescription Drugs," *Journal of the American Medical Association* 288, no. 14 (2002): 1733–1739; R.E. Johnson et al., "The Impact of Increasing Patient Prescription Drug Cost Sharing on Therapeutic Classes of Drugs Received and on the Health Status of Elderly HMO Members," *Health Services Research* 32, no. 1 (1997): 103–122; and T.S. Rector et al., "Effect of Tiered Prescription Copayments on the Use of Preferred Brand Medications," *Medical Care* 41, no. 3 (2003): 398–406.
5. A. Dor and W. Encinosa, "Does Cost Sharing Affect Compliance? The Case of Prescription Drugs," NBER Working Paper no. 10738 (Cambridge, Mass.: National Bureau of Economic Research, 2005); N. Lurie et al., "Termination of Medi-Cal Benefits: A Follow-Up Study One Year Later," *New England Journal of Medicine* 314, no. 19 (1986): 1266–1268; D.P. Goldman, G.F. Joyce, and P. Karaca-Mandic, "Varying Pharmacy Benefits with Clinical Status: The Case of Cholesterol-Lowering Therapy," *American Journal of Managed Care* 12, no. 1 (2006): 21–28; and R. Tamblyn et al., "Adverse Events Associated with Prescription Drug Cost-Sharing among Poor and Elderly Persons," *Journal of the American Medical Association* 285, no. 4 (2001): 421–429.
6. M. Angell, *The Truth about the Drug Companies: How They Deceive Us and What to Do about It* (New York: Random House, 2004).
7. P.M. Danzon, Y.R. Wang, and L. Wang, "The Impact of Price Regulation on the Launch Delay of New Drugs—Evidence from Twenty-five Major Markets in the 1990s," *Health Economics* 14, no. 3 (2005): 269–292; P.M. Danzon and J.D. Ketcham, "Reference Pricing of Pharmaceuticals for Medicare: Evidence from Germany, the Netherlands, and New Zealand," NBER Working Paper no. 10007 (Cambridge, Mass.: NBER, October 2003); and D. Acemoglu and J. Linn, "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry," *Quarterly Journal of Economics* 119, no. 3 (2004): 1049–1090.
8. A. Garber, C. Jones, and P. Romer, "Insurance and Incentives for Medical Innovation," *Forum for Health Economics and Policy* 9, no. 2 (2006): 1–27; and T. Philipson, S. Mechoulan, and A.B. Jena, "IP and External Consumption Effects: Generalizations from Health Care Markets," NBER Working Paper no. 11930 (Cambridge, Mass.: NBER, January 2006).
9. Goldman et al., "Varying Pharmacy Benefits."
10. J.S. Schultz et al., "Determinants of Compliance with Statin Therapy and Low-Density Lipoprotein Cholesterol Goal Attainment in a Managed Care Population," *American Journal of Managed Care* 11, no. 5 (2005): 306–312.
11. L. Wei et al., "Adherence to Statin Treatment and Readmission of Patients after Myocardial Infarction: A Six Year Follow Up Study," *Heart* 88, no. 3 (2002): 229–233.
12. A.M. Fendrick et al., "A Benefit-Based Copay for Prescription Drugs: Patient Contribution Based on Total Benefits, Not Drug Acquisition Cost," *American Journal of Managed Care* 7, no. 9 (2001): 861–867.