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Incentives to innovate and social harm: *Laissez-faire*, authorization or penalties?

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ABSTRACT

When firms' research can lead to potentially harmful innovations, public intervention may thwart their incentives to undertake research by reducing its expected profitability (average deterrence) and may guide the use of innovation (marginal deterrence). We compare four policy regimes: *laissez faire*, ex-post penalties and two forms of authorization – lenient and strict. If fines are unbounded, *laissez faire* is optimal if the social harm from innovation is sufficiently unlikely; otherwise, regulation should impose increasing penalties as innovation becomes more dangerous. If fines are bounded by limited liability, for intermediate levels of expected social harm it is optimal to adopt (indifferently) penalties or lenient authorization, while strict authorization becomes optimal if social harm is sufficiently likely.

1. Introduction

When private actions generate harmful externalities, public intervention can improve welfare if it appropriately trades off social harm reduction with enforcement costs, as recognized by a vast literature in public economics [1] and in law and economics.[2] Yet, it is rarely recognized that public intervention may stifle innovations that entail benefits as well as risks for society. Even though this idea dates back at least to the work of Friedrich Hayek (1935, 1940), to the best of our knowledge there is no formal analysis of how the design of public policies should take into account the risks and benefits stemming from private innovative activity.[3]

We address this issue, taking into account that public policies may affect both firms' effort to discover new technologies and their actual use, once discovered. Central to our approach is the idea that investment in research and development (R&D) often leads to innovations whose impact on welfare is unknown when the investment is made: not only research may fail to produce workable results, but even if it succeeds, it may lead to innovations with unpredictable welfare effects.

Since generally public policies penalize innovations that turn out to create social hazards, a firm undertaking R&D investment is uncertain as to how public policy will eventually treat the results of its research. Insofar as it expects policy to reduce the expected profitability of innovation, the firm will reduce its R&D investment – a disincentive effect that we label "average deterrence". As we will see, public policies may differ in average deterrence – their research-thwarting effect – as well as in marginal deterrence – their ability to steer innovators towards less harmful implementation of their findings. Precisely these differences dictate which policy is best in each circumstance.

Scientific uncertainty in R&D is an obvious example of the potentially two-edged effects of innovation: research on genetically modified (GM) seeds may pave the way to higher yields in farming, yet pose unknown risks to public health; similar issues arise in the nanotechnology industry (Biello, 2008; Scientific American, 2010) and in the pharmaceutical and chemical industries (Philipson and Sun, 2008). Another example refers to financial innovation: the introduction of new derivatives may open profit opportunities for intermediaries and offer new hedging tools for investors, while creating new dangers for

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[1] Several contributions in public economics highlight that intervention should be curtailed if its enforcement is very costly or generates bribery (Krueger, 1974; Rose-Ackermann, 1978; Banerjee, 1997; Acemoglu and Verdier, 2000; Glaeser and Shleifer, 2003; Immordino and Pagano, 2010, among others). Another strand of research deals with the optimal design of regulation (see Laffont and Tirole (1993) and Armstrong and Sappington (2007)).

[2] This strand of the literature has generated seminal contributions on optimal law enforcement such as Becker (1968), Becker and Stigler (1974) and Polinsky and Shavell (2000).

[3] An exception is the paper by Segal and Whinston (2007) on the impact of antitrust enforcement in high tech industries. Considering a sequence of innovations, the authors analyze the trade-off between protecting the incumbents, that increases the rents of the winner and the incentives to invest in innovation in the first place, and protecting the innovative entrants, that increases the rate of technical progress. They derive conditions under which the latter effect is the dominant one.

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unsophisticated investors who cannot master the information needed to invest in the new securities, as illustrated by the 2007–09 financial crisis. In the words of Lloyd Blankfein, CEO of Goldman Sachs, a key lesson of the crisis is that the financial industry "let the growth in new instruments outstrip the operational capacity to manage them. As a result, operational risk increased dramatically and this had a direct effect on the overall stability of the financial system" (Blankfein, 2009, p. 7).

In each of these situations, society may choose from a range of different regulatory responses. We focus on four different options: (i) *laissez faire*, (ii) a *lenient authorization* regime where inventions can be used commercially if not found to be harmful in tests, (iii) a *strict authorization* regime where they can be used commercially only if ascertained to be beneficial, and (iv) a regime based on *penalties*, where the commercial use of innovations is sanctioned *ex post* if found to be harmful. The difference between authorization and penalty-based regimes does not only lie in the timing of intervention – *ex-ante* scrutiny in the former *versus ex-post* evaluation in the latter – but also in their different degree of flexibility: authorization is a "yes-or-no" decision, and as such it admits no nuances, while penalties can be fine-tuned according to the severity and likelihood of social harm. But even an authorization regime can be designed to be lenient or strict, as just explained, depending on the standards of evidence required about the social effects of innovation.

We show that the greater the social harm that innovations may generate, the more cogent should be the chosen form of public intervention. This general principle applies first of all *within each regime*. When social harm is unlikely a lenient authorization regime is superior to a strict one, while the opposite holds when social harm is likely. Similarly, the penalty regime involves higher fines as the probability of harm increases: in the limiting case of very low risk of social harm, fines are optimally set at zero, effectively leading to a *laissez-faire regime*; as the risk of social harm increases, fines must be gradually increased so as to discourage increasingly harmful actions. This outcome is obtained by setting no fine for actions up to the one the regulator wants to implement, and deterring all other actions by fines large enough as to make them unprofitable. Hence, in the penalty regime, the regulator invariably induces firms to choose the welfare-maximizing action.

This result is no longer feasible if the maximum fine is capped, for instance because of limited liability. Then, penalties cannot deter firms from choosing the actions most harmful to society: these are precisely those yielding the highest profits, so that firms may wish to carry them out even at the risk of paying the maximum fine. In this case, therefore, the penalty regime becomes unappealing if the likelihood of social harm is very high.

The principle that the cogency of public intervention should be increasing in the likelihood of social harm also applies to the choice *across regimes*. If there is no upper bound on fines, society should opt either for *laissez-faire* or for the penalty regime, depending on the likelihood of social harm. In this case, the blunter authorization regimes are invariably dominated. If instead fines are constrained by limited liability, authorization regimes will be preferred when the risk of social harm is sufficiently large. More specifically, in this case the full range of regimes is deployed, depending on the risk level: *laissez-faire* if risk is very low; the penalty regime if risk is in an intermediate range (or equivalently lenient authorization in the top portion of this range); finally, strict authorization for high risk levels. In general, these optimal policies entail underinvestment in research compared to the first-best level, since firms do not internalize the social benefits of innovation (although overinvestment in innovation may occur in the penalty regime when fines are bounded by limited liability).

These policies are softer than those that should be adopted if innovation did not require costly investments in R&D. In that case, regulation would not need to trade off the social risk of social harm with the firm's incentives to innovate, so that only marginal deterrence would matter: *laissez faire* would never be adopted, and in the penalty regime the regulator would deter any harmful action as long as sufficiently high fines are feasible, rather than gradually restricting the firm's choice to less damaging actions as the probability of social harm increases, as done when R&D is costly.

The empirical evidence is consistent with a key prediction of the model – that authorization regimes should be used and become more cogent only when potential social harm is large. In overseeing the safety of medical devices, the FDA authorization process requires more stringent review processes depending on the relevant degree of patient risk.[4] The same principle is now advocated to regulate financial innovation: while the safest securities should be available to investors without authorization, riskier ones, such as derivatives or structured debt, should be sold only upon being authorized, and even so only to eligible investors and in limited amounts.[5] Furthermore, authorization regimes have typically become more stringent when regulators have realized that the likelihood of social harm had been underestimated: the FDA and the European Medicine Agency (EMA) tightened their standards and protocols to authorize drugs since Thalidomide (a morning sickness pill) caused thousands of children in Europe to be born with birth defects in the 1960s.[6]

A second prediction of the model – that tougher regulation comes at the cost of lower incentives to innovate – is also supported by the evidence. The increasingly costly and lengthy clinical trials required by the FDA have prompted growing concerns over the incentives to introduce new drugs: "Ray Hill, president of the British Pharmacological Society … cautions that the much higher costs and larger trials risks reducing pharmaceutical research and stunting innovation. For example, the entire class of Cox 2 painkillers […] was in effect killed by the withdrawal, as the FDA began to demand much bigger pre-approval trials" (Financial Times, 2010b). This outcome would be in line with evidence from the 1960s and 1970s: the annual number of introductions of new chemical entities per dollar of R&D expenditure in the U.S. declined by about sixfold between 1960–61 and 1967–70, while the corresponding figure in the U.K. was threefold. A comparative analysis of these two countries' experience concludes that, controlling for other factors, increased and tighter regulation after 1962 contributed to the slowdown in the innovativeness of the U.S. pharmaceutical industry (Grabowski et al., 1978).

At a theoretical level, our analysis is related to Shavell (1984), who analyzes four determinants of the choice between an authorization and a penalty regime, in his context respectively labeled as safety regulation and liability: (i) difference in risk knowledge; (ii) incentive or ability to enforce penalties; (iii) magnitude of administrative costs, and (iv) magnitude of maximal fines. In our analysis, we hold determinants (i) to (iii) constant across regimes. This is done to focus on the role of innovation in the choice between regimes, eliminating other sources of differential effectiveness between them.

Our model also shares some features with the "activity level" model of law enforcement (Shavell, 1980, 2007; Polinsky and Shavell, 2000). In that model, private benefits and social harm depend on two

[4] The FDA categorizes devices "in one of three classes (I, II, and III), based on the degree of patient risk. Class I devices are the least risky, and typically require no premarket approval from the FDA, although the manufacturer must register with the FDA prior to marketing the device. Class II devices pose more risk to patients, and must receive prior approval via the 501(k) review process, which typically seeks to establish that the given device is substantially equivalent to another device that has received FDA approval. The most risky (class III) devices require approval via the premarket approval process (PMA), which, similar to the process for pharmaceuticals […], involves the submission of a PMA application establishing the device's safety and efficacy, usually through the results of clinical trials" (Philipson at al., 2010, p. 8).

[5] Stephen Cecchetti (Head of the Monetary and Economic Department of the BIS) argues that, just like drugs must undergo clinical testing before being authorized for sale, financial offerings would be subject to similar tests before being authorized: "An instrument could move to a higher category of safety only after successful tests analogous to clinical trials" (Financial Times, 2010a).

[6] "Thalidomide marked a turning point in the history of drug regulation, leading the authorities around the world to impose higher approval standards to insure drugs were tested for safety as well as efficacy" (Financial Times, 2010b).