Journal of Public Economics 167 (2018) 21–32

Contents lists available at ScienceDirect

Journal of Public Economics

journal homepage: www.elsevier.com/locate/jpube

The enforcement of mandatory disclosure rules☆

Matthias Dahm[a,*], Paula González[b], Nicolás Porteiro[b]

[a] University of Nottingham, School of Economics, University Park, Nottingham NG7 2RD, UK
[b] Universidad Pablo de Olavide, Department of Economics, Spain

ARTICLE INFO

Article history:
Received 13 January 2017
Received in revised form 13 July 2018
Accepted 23 August 2018
Available online xxxx

JEL classification:
D82
L15

Keywords:
Strategic information transmission
Scepticism
Confidence effect
Monitoring
Penalty
Fine
Sanction
Detection probability

ABSTRACT

This paper examines the incentives of a firm to invest in information about the quality of its product and to disclose its findings. If the firm conceals information, it might be detected and fined. We show that optimal monitoring is determined by a trade-off. Overall, stricter enforcement reduces the incentives for selective reporting but crowds out information search. Our model implies that there are situations in which the relationship between the two monitoring instruments might be complementary. We also show that the welfare effects of mandatory disclosure depend on how it is enforced and that imperfect enforcement (in which some information remains concealed) might be optimal. In particular, the optimal fine might be smaller than the largest possible fine, even though the latter requires lower resource costs for inspections.

1. Introduction

> *The US FDA Amendment Act 2007 requires that results must be posted on clinicaltrials.gov within a year of the completion of the trial for all trials with at least one site in the US. The FDA has the power to fine trial sponsors who do not comply but rarely does this … The proposed EU Clinical Trials Regulation will require that summary results for every registered trial must be posted within one year of the completion of the trial, and the European Commission is discussing how to enforce this properly. Trial approval bodies in each country should consider expanding their monitoring of reporting, and ensure there is routine and open public audit of compliance for each individual trial.* - The AllTrials Campaign[1]

In September 2004, the pharmaceutical company Merck voluntarily withdrew Vioxx–a pain medication for arthritis–from the world market, because a clinical trial indicated that it increased the risk of heart attacks and strokes when taken for at least 18 months. Later, however, it was discovered that the company had failed to warn of the drug's dangers before the withdrawal. Following several scandals of so-called selective reporting of clinical trial results, the Food and Drug Administration Amendments Act (FDAAA) included

☆ We would like to dedicate this paper to our co-author Nicolás Porteiro who passed away in April 2012. We are truly grateful for his friendship over many years and for all that we learned from him during that time. We are indebted to Inés Macho-Stadler, David Pérez-Castrillo and Daniel Seidmann for their careful reading of this paper. We are also grateful for valuable comments and suggestions from Helmut Bester, Farasat Bokhari, Subhasish M. Chowdhury, Thomas Gall, Paul Heidhues, Roberto Hernán-González, Navin Kartik, Sang-Hyun Kim, David Myatt, Pau Olivella, Carmelo Rodríguez-Álvarez, Marta Ronchetti, Roland Strausz, Marcos Vera-Hernández and Ansgar Wohlschlegel. Financial support from Fundación Ramón Areces is gratefully acknowledged. This work is partially supported by the research projects ECO2012-36480 and ECO2015-65408-R (Ministerio de Ciencia y Tecnología) and FEDER. All errors are our sole responsibility.

* Corresponding author.
E-mail addresses: Matthias.Dahm@nottingham.ac.uk (M. Dahm), pgonzalez@upo.es (P. González).

[1] The AllTrials campaign was launched in 2013 and at the time of writing has been signed by 93403 people and 740 organisations, see www.alltrials.net, accessed on 08/06/2018.

https://doi.org/10.1016/j.jpubeco.2018.08.014
0047-2727/

the requirement of basic result reporting. Mandatory disclosure rules have also been established in other areas . For instance, manufacturers of SUVs are required to report rollover risk in the US. This regulation followed an inquiry into a series of deadly accidents during which it was found that the tire manufacturer Bridgestone/Firestone and the auto company Ford had failed to inform the public about the risk of Ford Explorer SUVs rolling over after tires blew out without warning.[2]

The above quote argues that mandatory disclosure rules for clinical trials should be complemented by strict enforcement. Considering monitoring through penalties and appropriate resources to conduct inspections, our research question is to identify the effects of such an enforcement.[3] Our results uncover a trade-off that optimal enforcement must balance and that policy discussions seem to be unaware of.

We consider an information transmission game with hard evidence between a firm and the public (Milgrom, 1981; Grossman, 1981; Milgrom and Roberts, 1986; Seidmann and Winter, 1997). Hence it is not possible to fabricate the entire evidence of a clinical trial. The firm's product is either effective or has side-effects. A clinical trial potentially reveals these consequences to the firm. We allow for the possibility that the firm is not informed, so that the classical unravelling argument is mitigated (Dye, 1985; Shin, 1994). Consequently, a clinical trial can either be positive, negative or inconclusive (De Angelis et al., 2004). As with Shin's sanitization strategy, negative trials are suppressed and positive ones revealed, so that selective reporting is obtained in equilibrium.

The firm is required to disclose quality and safety problems. A monitoring agency invests resources in inspections and imposes a fine on the firm when it discovers that the firm conceals information. Enforcement is hence captured by a combination of a probability of detection and a fine.[4] Inspired by the Food and Drug Administration (FDA) that controls production plants and searches for contamination problems of which the seller might or might not be aware, the agency detects with some probability the existence of quality and safety problems. If this is the case, it also learns if information was concealed. An extension considers the case in which the agency does not search for information on the state of the world but detects selective reporting directly.

Selective reporting is considered to be harmful to society.[5] It might therefore appear that we can gain insights into optimal enforcement by drawing an analogy to law enforcement. Following Becker (1968) the deterrence of a harmful act depends on the expected fine. Moreover, it is optimal to combine a low probability of detection with the highest possible fine, for, if the fine were not as high as possible, then one could simultaneously increase the fine and decrease the probability of detection, thereby reducing enforcement costs. In this paper, however, we show that optimal enforcement in our context and in law enforcement differs in important ways. In particular, the largest possible fine might not be optimal, even though it requires fewer resources for inspections.

One difference between the two settings is that the firm's profits from concealing information depend on the monitoring policy. This is so, because the firm's profits depend on the beliefs of the public about the quality of its product. When no hard evidence is revealed these beliefs depend on the interplay of two effects. On the one hand, the failure of the firm to disclose positive information makes the public more pessimistic, as it is aware that information might be withheld. We refer to this as the *scepticism effect* of a lack of evidence.[6] On the other hand, if monitoring does not find concealed information, then the public becomes more optimistic; and the higher the probability of detection, the more optimistic the public becomes. We call this the *confidence effect* of monitoring.

Another difference between the two settings is that the firm has two alternatives to concealing evidence. The intended effect is to induce the firm to reveal its evidence honestly. But monitoring can also have the unintended effect of stopping the firm to acquire information in the first place. We denominate the latter as the *disincentive effect* of monitoring on information search and show that it might deter both honestly and selectively reported information. The incentive to invest in the former declines, as the confidence effect raises the opportunity costs of information. The incentive to invest in the latter declines, because stricter enforcement increases the expected fine.

It is well known that when enforcement is exogenous, a change from voluntary to mandatory disclosure reduces the incentives to invest in information.[7] It is also well known that the strength of this disincentive effect depends on the shape of the firm's profit function.[8] In our model the precise condition for the disincentive effect not to crowd out investment in information completely is a generalization of convexity of the profit function that allows for both convex and concave segments. We assume that the firm's profit function is a general function of the public's beliefs but provide a micro-foundation for a convex relationship when treatment effects are more likely to be moderate than strong.[9]

Our first contribution is to deepen our understanding of the disincentive effect. Optimal monitoring is determined by a trade-off. Stricter enforcement reduces the incentives for selective reporting but crowds out information search. We add to the literature that this trade-off between the quality and the quantity of information is overall robust to endogenizing enforcement but that it depends

[2] On Vioxx see Berenson (2006), Antman et al. (2007) or Krumholz et al. (2007). On the FDAAA of September 2007 see Wood (2009). A detailed account of the SUV rollover scandal and the development of the Transportation Recall Enhancement, Accountability, and Documentation Act (TREAD) of November 2000 can be found in Fung et al. (2007). This book also discusses 17 other policy areas in which mandatory disclosure rules exist, including corporate financial disclosure, nutritional labelling and restaurant hygiene disclosure. Dranove and Jin (2010) offer further background on disclosure including a brief history.

[3] Fung et al. (2007) discuss (on pp. 45–46) in detail the need for appropriate enforcement through monitoring and levying penalties. The FDAAA allows for civil penalties of as much as $10 000 per day but this is considered to be insufficient, see Prayle et al. (2012), Anderson et al. (2015) or Gopal et al. (2015). As a result, there are calls for greater transparency in clinical trials, including Chan et al. (2014), Goldacre (2013), Hudson and Collins (2015), and the aforementioned AllTrials on-line petition.

[4] The agency can also be thought of as a surrogate for indirect enforcement like litigation, whistle-blowing, political activism or journalistic investigations. Under this interpretation, different institutional designs of liability trials, confidentiality agreements, and legal protection for whistle-blowers might be related to different magnitudes of the probability of detection.

[5] For the case of clinical trials De Angelis et al. (2004, p. 477) write "The case against selective reporting is particularly compelling for research that tests interventions that could enter mainstream clinical practice. …When research sponsors or investigators conceal the presence of selected trials, these studies cannot influence the thinking of patients, clinicians, other researchers, and experts who write practice guidelines or decide on insurance-coverage policy."

[6] When the firm is known to be informed, this effect leads to the classical unravelling result.

[7] See Matthews and Postlewaite (1985), Farell (1986), Shavell (1994), Dahm et al. (2009), Henry (2009), Polinsky and Shavell (2012), Kartik et al. (2017) and Schweizer (2017).

[8] As Kartik et al. (2017, p. 27) observe, "the martingale property of Bayesian updating implies that experts would gain nothing by acquiring information" when payoffs depend linearly on these beliefs.

[9] There is also suggestive evidence that such a relationship is not unrealistic. Grabowski et al. (2002) estimated a highly skewed distribution of returns (net present values) for new drug introductions. More precisely, the top decile of most successful new drugs accounted for a 52% of the total present value generated by all new drugs. This seems to suggest that the market rewards higher quality at a highly increasing rate. Moreover, it seems that this pattern has not changed over time. Grabowski and Vernon (1994) found a highly skewed distribution of returns for the 1980–1990 period. In this study, the top two deciles accounted for more than a 70% of the total net present value.