RESEARCH LETTER

Financial Penalties Imposed on Large Pharmaceutical Firms for Illegal Activities

Some pharmaceutical companies have received criticism for engaging in illegal activities, such as providing kickbacks and bribes, knowingly shipping adulterated or contaminated drugs to pharmacies, and marketing drugs for unapproved uses. This study examined financial penalties for illegal activities among large pharmaceutical firms in relation to annual revenues.

Methods | We collected data on financial penalties for pharmaceutical firms listed on the Global 500 or Fortune 1000 lists using procedures similar to Almashat et al.[1] Consistent with prior research,[2] we analyzed all firms that met inclusion criteria and appeared on the list for 7 years or more. All instances of financial penalties from state and federal settlements between January 2003 and December 2016 were obtained from the US Department of Justice, the US Securities and Exchange Commission, the US Environmental Protection Agency, and states' attorneys general. Each settlement included the penalty amount and described the scope, type, and duration of the associated illegal activity. We secured missing data through Freedom of Information Act requests. Financial penalties were attributed to the settlement year.

To adjust for inflation, we calculated the cumulative dollar value of each firm's financial penalties for each year and applied the Bureau of Economic Analysis' Gross Domestic Product Deflator to convert the cumulative amount to 2016 dollars. When firms merged with or were acquired by other firms during the study period, we attributed all penalty settlements, both before and after acquisition, to the firm that engaged in the illegal activity. We calculated the mean penalty amount by dividing the total dollar value of each company's financial penalties by the total number of penalties levied during the study period. We calculated the total dollar value of each company's financial penalties as a percentage of their total revenues during the study period using data from Compustat, Mergent Online, Edgar Direct, and annual reports filed with the Securities and Exchange Commission. We provided the mean duration of illegal activity for penalties settled during the study period. We used content analysis to classify each settlement into 1 or more types of illegal activity and summarized the frequency by firm and illegal activity type.

Results | Among 26 firms in our sample, 22 (85%) had financial penalties for illegal activities. The combined dollar

Table 1. Value of Financial Penalties and Duration of Illegal Activity

Company[a]	Value of penalties, total $, in thousands[b]	No. of penalties	Penalty amount, mean $, in thousands	Penalties, % of total revenues (rank)[c]	Duration of illegal activity associated with penalties, mean, y
GlaxoSmithKline	9 775 419	27	362 053	1.55 (2)	7.22
Pfizer	2 910 581	18	161 699	0.36 (11)	5.67
Johnson & Johnson	2 668 326	15	177 888	0.28 (13)	6.08
Abbott Laboratories	2 581 585	11	234 690	0.75 (6)	6.36
Merck	2 094 026	11	209 403	0.40 (9)	6.13
Eli Lilly	1 775 031	7	253 576	0.59 (7)	6.14
Schering-Plough[d]	1 645 186	12	137 099	2.05 (1)	6.18
Wyeth[d]	1 614 355	7	230 622	1.15 (4)	8.71
Bristol Myers Squibb	1 389 197	12	115 766	0.50 (8)	5.83
Novartis	1 198 088	11	108 917	0.18 (16)	6.55
AstraZeneca	1 172 185	10	117 219	0.28 (14)	8.30
Amgen	945 034	9	105 004	0.39 (10)	9.78
Allergan[d]	660 604	1	660 604	1.16 (3)	7.00
Bayer	602 688	13	46 361	0.09 (19)	4.00
Mylan	227 800	6	37 967	0.30 (12)	4.67
Sanofi-Aventis	535 923	10	53 592	0.10 (18)	6.50
Boehringer Ingelheim	416 439	7	59 491	Not applicable[e]	5.86
Forest Laboratories[d]	383 452	3	127 817	0.88 (5)	5.33
Actavis (Watson)	77 312	2	38 656	0.09 (17)	11.00
Roche Group	67 000	1	67 000	0.01 (21)	5.00
Genzyme[d]	56 152	2	28 076	0.19 (15)	5.00
Perrigo	7816	1	7816	0.02 (20)	1.00

[a] Four firms were not found to have penalties for illegal activities during the sample period: Biogen Idec, Celgene, Gilead Sciences, and Hospira.

[b] Total dollar value from 2003 through 2016, adjusted for inflation in 2016 dollars (the last year of data collection).

[c] Sum of yearly revenues for the duration of firm existence over the study period (2003-2016), adjusted for inflation in 2016 dollars.

[d] Six companies were acquired before 2016: Forest Laboratories in 2014 and Allergan in 2015 (acquired by Actavis [Watson]), Schering-Plough in 2009 (acquired by Merck), Wyeth in 2009 and Hospira in 2015 (acquired by Pfizer), and Genzyme in 2011 (acquired by Sanofi).

[e] Boehringer Ingelheim is private. Revenues were not available to calculate penalties as a percentage of revenue.

Table 2. Type and Frequency of Illegal Activity Associated With Penalties

Company[a]	No. of penalties	Violation frequency										
		Adulterated drugs[b]	Bribery[c]	Competition[d]	Disclosure[e]	Environmental violations[f]	Financial violations[g]	Kickbacks[h]	Misleading marketing[i]	Off-label marketing[j]	Pricing[k]	Uncategorized[l]
GlaxoSmith Kline	27	2	2	3	5	3	1	2	5	3	11	1
Pfizer	18	0	2	0	1	4	0	1	7	5	3	0
Johnson & Johnson	15	1	1	0	5	0	0	4	4	9	2	0
Bayer	13	0	0	3	1	4	0	1	3	1	4	0
Schering-Plough[m]	12	0	0	0	2	0	2	1	1	1	8	0
Bristol Myers Squibb	12	0	1	4	1	1	2	1	1	2	3	0
Abbott Laboratories	11	0	0	2	1	2	0	3	1	1	4	0
Merck	11	0	0	0	2	2	1	2	1	2	7	1
Novartis	11	0	1	0	1	0	1	5	0	4	5	0
AstraZeneca	10	0	1	0	1	0	0	4	1	2	6	1
Sanofi-Aventis	10	0	0	2	0	1	0	2	0	0	6	0
Amgen	9	0	0	0	0	1	0	3	1	3	5	0
Boehringer Ingelheim	7	0	0	0	0	2	0	1	1	1	4	0
Eli Lilly	7	0	0	0	1	0	0	1	1	7	1	0
Wyeth[m]	7	0	1	0	0	1	0	0	2	4	1	0
Mylan	6	0	0	1	0	0	0	0	1	0	4	0
Forest Laboratories[m]	3	1	0	0	0	0	0	2	0	1	1	1
Actavis (Watson)	2	0	0	0	0	0	0	0	0	0	2	0
Genzyme[m]	2	1	0	0	0	0	0	0	1	2	1	0
Allergan[m]	1	0	0	0	0	0	0	0	0	1	0	0
Roche Group	1	0	0	0	0	0	0	0	1	1	0	0
Perrigo	1	0	0	1	0	0	0	0	0	0	0	0
Total		5	9	16	21	21	7	33	32	50	78	4

[a] Biogen, Celgene, Gilead Sciences, and Hospira had no violations in this period.

[b] Manufacturing and distributing adulterated or unapproved drugs.

[c] Bribery to foreign officials, suppliers, or other entities.

[d] Fraudulently delaying market entry of competitors, antitrust, monopoly.

[e] Failure to disclose negative information about a product or about poor drug development.

[f] Violations of environmental regulation(eg, Clean Air Act).

[g] Tax fraud and insider trading.

[h] Offering kickbacks to suppliers or customers to purchase and sell their product(s).

[i] Misleading or deceptive marketing practices.

[j] Advertising a product for uses other than approved by the US Food and Drug Administration.

[k] Overpricing drugs reimbursed or paid for by government, underpaying rebate obligations, fraudulent pricing or billing, or other pricing illegalities.

[l] Violations that do not fit the other reported categories.

[m] Company was acquired before 2016. See footnote d in Table 1.

value of financial penalties totaled $33 billion for 2003 to 2016. Eleven firms with financial penalties exceeding $1 billion in inflation-adjusted dollars accounted for $28.8 billion (88%) of the total penalties (**Table 1**). The firms with the highest penalties as a percentage of revenues (ie, >1%) were Schering-Plough, GlaxoSmithKline, Allergan, and Wyeth; the number of penalties for these firms varied between 1 (Allergan) and 27 (GlaxoSmithKline). Four firms had financial penalties that totaled less than $80 million and no more than 2 penalty settlements (Actavis [Watson], Roche Group, Genzyme, and Perrigo). All but 1 firm (Perrigo) engaged in illegal activities associated with penalties for 4 or more years. An additional 4 firms received no financial penalties for illegal activities during this period. The most common types of illegal activity involving penalties (**Table 2**) were pricing violations, off-label marketing, and kickbacks. The firms with the greatest variety in the types of illegal activities involving penalties were GlaxoSmithKline, Bristol Myers Squibb, and Merck. Three firms (Actavis, Allergan, and Perrigo) had penalties limited to a single violation type.

Discussion | Among the large pharmaceutical companies included in this study, 85% had evidence of financial penalties for illegal activities. Given the scope and nature of the illegal activities involving financial penalties, physicians and regulators should exhibit vigilance over the activities of large pharmaceutical firms. Four firms were not found to

have penalties for illegal activities during the sample period. This may indicate an ability for illegal activity to be undetected, although these firms may instead have effective ethics and compliance programs.[3,4]

Limitations of the study include focus on the largest firms, exclusion of class-action settlements and penalties by non-US governments, and the possibility that some settlements were missed. Also, only settlements from a limited time period were examined; whether these data reflect current activities of pharmaceutical companies or whether financial penalties for illegal activities have increased or decreased more recently could not be determined. Other industries also engage in illegal activities, but a comparative analysis is beyond the scope of this study.

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COMMENT & RESPONSE

Assessing Alternative Payment Models

To the Editor Dr Navathe and colleagues suggested that alternative payment models have played a key role in slowing the growth of US health care spending despite evidence indicating they have limited effect.[1] They posited that the true effect of alternative payment models has been underestimated in individual evaluations because these models have been compared with a declining spending baseline.

Their considerations raise doubt about whether evaluations of alternative payment models to date provide a clear and complete picture of their effects. At the same time, we believe these concerns underscore the urgent need for the Centers for Medicare & Medicaid Services (CMS) to move toward more rigorous forms of policy evaluation.

Although CMS has implemented new alternative payment models at an unprecedented pace, they have primarily relied on retrospective, observational analyses to examine these models, which have limitations. As a result, clinicians, health systems, and policy makers have often been left with greater uncertainty, rather than clarity, about what does and does not work.

Incorporating randomized clinical trials (RCTs) into evaluations of alternative payment models, using traditional cluster, stepped-wedged, and/or adaptive designs, could produce a higher quality of evidence for policy makers seeking to scale promising models.[2,3] Doing so could mitigate the concerns Navathe and colleagues raised about peer effects and control group contamination potentially influencing estimates of the effects of alternative payment models. Unfortunately, randomized evaluations of alternative payment models, like those proposed for cardiac bundled payments, have been scaled back rather than expanded by CMS in recent years.[4]

In the absence of RCTs, policy makers are forced to make decisions based on imperfect evaluations with uncertain results, making alternative explanations—like the ones Navathe and colleagues proposed—plausible. Clinicians and health systems invest considerable resources to participate in alternative payment models, often at an opportunity cost, and new incentives under these programs can influence patient care for better or worse. Therefore, CMS should adopt a higher standard for evidence generation. Using randomization to understand whether new models lead to improvements in care delivery, or unintended repercussions, would better inform which models should be expanded, refined, or eliminated.[5]

The last decade of innovation in value-based care has been defined by experimentation with new payment models. Over the next decade, CMS should shift from experimental to evidence-based policy by prioritizing rigorous, randomized evaluations of promising models, to ensure that they are effective and improve patient care, prior to widespread implementation.

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