

# Mandatory disclosure of all pharmaceutical and medical device companies' payments to healthcare providers: learning from the USA

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## Introduction

Throughout history, people have attempted to influence others by offering money, goods or services. If such influence-peddling had not been so successful, it might have vanished long ago. However, following Darwinian principles, it has progressively evolved, becoming more prevalent, complicated, extremely successful and, too often, damaging to people who, unaware of influence-peddling schemes, become their victims.

The most succinct argument for transparency of influence-intended financial transactions was made over 100 years ago when former US Supreme Court Justice Louis Brandeis said, 'Publicity is justly commended as a remedy for social and industrial diseases. Sunlight is said to be the best of disinfectants'.<sup>1</sup>

## What is the problem?

As the practice of medicine evolved into what former *New England Journal of Medicine* editor Arnold Relman called the 'new medical-industrial complex' (a term first used by health policy experts Barbara and John Ehrenreich in the November 1969 issue of the *Bulletin of the Health Policy Advisory Center* in an article entitled 'The Medical Industrial Complex' and in a subsequent book, *The American Health Empire: Power, Profits, and Politics*)<sup>2</sup> with increasing use of private companies to supply healthcare services to patients for a profit, a larger percentage of health expenditures are spent on pharmaceuticals and medical devices.<sup>2</sup> Not content with merely influencing physicians and other health professionals via advertising, these industries also offer free meals, vacations and, more expensively, well-paying speaking and consultant fees. Such conflict of interest has been described as 'a set of

circumstances that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest'.<sup>3</sup>

By the end of the first 6 years of government-mandated industry Open Payments Database (OPD) disclosure (2014–2019), US physicians, also defined as including dentists, podiatrists, optometrists and chiropractors,<sup>4</sup> had been given more than \$18 billion of 'general payments', payments that include, but are not limited to, honoraria, gifts, meals, consulting fees and travel compensation.<sup>5,6</sup> The value of all general payments has increased from \$2.7 billion in the first full year, 2014, to \$3.6 billion in 2019.<sup>6</sup> Each year, more studies document the clear relationship between general OPD payments to physicians and their influence on their pharmaceutical and medical device prescribing practices. In addition, during 2014–2019, \$32.4 billion in OPD-listed industry research payments were made. This total includes payments for which the company making the payment has named a physician as the primary recipient as well as other payments to a research institution or entity where a physician, though named as a principal investigator on the research project, does not receive an industry payment.<sup>6</sup> Any possible influence of these research payments on prescribing has not been quantified, probably because of confounding with the much more common general payments in the OPD for many physicians.

A 2019 study compared opioid-related payments to physicians from pharmaceutical manufacturers with their prescribing data for those opioids, by correlating physicians' OPD payments from specific companies with publicly available companies' drug-specific prescriptions they wrote for Medicare patients with part D

drug coverage.<sup>7</sup> During the 29-month study period, there were 416 678 payments to 63 941 physicians, totaling \$36.27 million, mainly for speaker fees (\$22.42 million) and food and beverage (\$6.92 million). Opioid-related payments were associated with a significantly higher likelihood of exceeding prescribed dosages of 90 morphine milligram equivalents/day (a dose of morphine that is equivalent to the dose of the prescribed opioid),<sup>8</sup> doses that the US Centers for Disease Control and Prevention chronic pain opioid-prescribing guidelines recommend avoiding.<sup>7,8</sup> Increased payments were also associated with a greater likelihood that patients who were neither under the care of a hospice nor had cancer were being prescribed opioids at these same higher dosages.<sup>7</sup>

A similar approach examined the relationship between industry payments and gastroenterologists' prescribing of the biological medications adalimumab (Humira) and certolizumab (Cimzia), accounting for most outpatient treatment expenditures for inflammatory bowel diseases Crohn's disease and ulcerative colitis, with a total of \$621 million in Medicare expenditures for adalimumab alone from 2014 to 2016.<sup>9</sup> Using linear regression, the authors used the value of payments from drug manufacturers as the exposure and Medicare spending on biological prescriptions as the outcome. From 2014 to 2016, 75% of 3737 prescribing gastroenterologists received industry payments. The OPD included \$10.5 million in payments to gastroenterologists prescribing adalimumab, with more than 98% of payments for either food, travel and lodging expenses, or speaking and consulting, and 0.12% for education. For every \$1 in payments to physicians,

there was a statistically significant \$3.16 increase in spending for adalimumab. For consulting and speaking payments, every \$1 was associated with a \$3.55 increase in spending for adalimumab, for food, travel and lodging.<sup>9</sup>

The correlation between medical device industry payments to physicians implanting heart defibrillators and physicians' decision of which defibrillator to implant has also been documented.<sup>10</sup> Over a 3-year period, 145 900 US patients received implantable cardioverter-defibrillator or cardiac resynchronisation therapy-defibrillator (CRT-D) devices from four different manufacturers, implanted by 4435 physicians. Among these physicians, 4152 (94%) received payments totaling \$20 406 474 per year from these device manufacturers, ranging from \$2 to \$323 559, with an average annual payment of \$4915. Significantly more patients received devices from the same manufacturer that had provided their physician with the largest payments than from the other three manufacturers.<sup>10</sup>

A systematic review of published studies analysed whether receipt of payments from industry was directly associated with physician prescribing practices.<sup>11</sup> In 30 of the 36 studies (83 per cent), a positive association between payments and prescribing was found. Increasing payments were associated with increased prescribing of the paying company's drug, prescribing costs and increased prescribing of branded drugs. The authors concluded by stating 'our results support the conclusion that personal payments from industry reduce the ability of physicians to make independent therapeutic decisions and that they may be harmful to patients. The medical community must change its historical opposition to reform and call for an end to such payments'.<sup>11</sup>

Until 2009, US pharmaceutical company payments to health professionals were closely held trade secrets. However, several companies began reporting the information publicly as a condition of settling federal whistle-blower lawsuits. A group of health journalists working for ProPublica began publishing such data several years before the OPD was available.<sup>12</sup> Previously introduced unsuccessfully as the Physician Payment Sunshine Act of 2007, the Open Payments programme was finally enacted as part of the Patient Protection and Affordable Care Act in 2010. It requires that manufacturers that operate in the USA and do business

with Medicare—such as pharmaceutical and medical equipment companies—must regularly report their payments to teaching hospitals and US-licensed physicians, including dentists, podiatrists, optometrists and chiropractors.<sup>13</sup>

In the autumn of 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) was signed into law. The SUPPORT Act expands the Open Payments definition of a covered recipient to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anaesthetists and anaesthesiologist assistants and certified nurse midwives.<sup>14</sup> The first publicly posted data from all companies are now being collected.

### Can full public disclosure be accomplished?

In the USA, full public disclosure does not depend on voluntary reporting by doctors of these payments, since those most in need of public scrutiny may not volunteer. Legally required complete disclosure to the OPD by the companies themselves eliminates such incomplete voluntary disclosure and is available for anyone to access.<sup>15</sup> Equally important is availability in an easily searchable user-friendly format. A recent review of voluntary industry reporting of payments to health professionals in seven European countries found that 'in no country did self-regulation generate comprehensive individualized data allowing for building an accurate picture of financial relationships between the industry and healthcare professionals', concluding that 'the study supports calls for a Europe-wide "Sunshine Act" to achieve real transparency of drug company payments'.<sup>16</sup> In the UK, because there is only voluntary reporting by industry and physicians, 'it is not easy to find information on the relationship (financial or otherwise) between pharmaceutical and medical device companies, and clinicians, healthcare providers...', even though 'there is support for mandatory reporting from most organisations that represent doctors'.<sup>17</sup>

The adverse effects of the large disclosure gap between mandatory and voluntary payments in the USA were documented by comparing OPD payments for 200 OPD-listed physician authors of articles published in high-impact clinical neurology journals with authors' self-disclosed journal payments.<sup>18</sup> Of 2239 general payments from 2013 to 2016 to these authors, from companies making products directly tested or discussed in their article, 970 (43%) were

not disclosed by authors. The total value of all such payments was \$2.753 million, of which \$1.665 million (60.5%) was not disclosed. The average general payment per author was \$114 722, with the maximum of \$876 952 for a single author. The study's authors concluded that 'Industry-related financial relationships are prevalent among United States-based physicians publishing in major neurology journals, and incomplete self-disclosure is common.....academic and other neurologists must work to establish firm rules to ensure and manage disclosure of financial COI'.<sup>18</sup>

### Why is disclosure alone not enough?

Although disclosure of these gifts is truly a sine qua non, it is not enough, especially if it is neither seen, understood by enough people nor acted on. Most patients in the USA are unaware of either the existence of the OPD or the increasing evidence that physician recipients of these effectively aimed pharmaceutical and device industry payments also prescribe more of their drugs and devices, potentially impacting patients' personal health. An excellent review of important studies documenting the impacts of these payments on physicians' practices concluded that 'Financial COI is corrosive and eats away at the basic function of medicine—to deliver quality care to patients. Declaring conflicts is only the first step in dealing with this problem', but 'Disclosure is not enough. The ultimate solution is to eliminate all industry relationships from the practice of medicine'.<sup>19</sup>

### Other needed actions

Studies correlating pharmaceutical and device manufacturer payments to physicians with those physicians' prescriptions of those corporate healthcare drugs and medical devices must continue. The potential health and financial impacts of these findings must also be more clearly and frequently translated into a teachable form, helping to educate patients and practising physicians on the value of learning more about physicians' practice of medicine and prescribing intent. For physicians wishing to refer patients to a certain specialist, performing an open payments background check on that specialist could be enlightening.

Beyond informing patients and physicians at a personal level, current federal laws prohibit many of these damaging activities but have not been vigorously enforced, damaging the US government's ability to reduce, if not eliminate, all industry relationships from the

practice of medicine. Since whistle-blowing is one of the most effective ways to prevent and detect breaches of law, its increasing use in the USA, along with better enforcement of other antifraud laws, must complement the OPD in significantly reducing, if not eliminating, industry financial relationships with healthcare providers.

In 1863, because of widespread fraud by government contractors during the Civil War, Congress passed the False Claims Act (FCA), which included a provision promising whistle-blowers a percentage of the money recovered by the government. Subsequent amendments weakened the effectiveness of the law, resulting in its diminished use to combat fraud against government programmes. In 1986, the FCA was formally amended to more effectively encourage whistle-blowers to come forward.<sup>20</sup> The US Department of Justice (DOJ) has said 'Whistleblowers with insider information are critical to identifying and pursuing new and evolving fraud schemes that might otherwise remain undetected'.<sup>21</sup>

The Federal Anti-Kickback Statute makes it a criminal offence to knowingly and willfully solicit, receive, offer or pay any remuneration to induce or reward, among other things, referrals for, or orders of, items or services reimbursable by a federal healthcare programme.<sup>22</sup> In October 2020, medical device manufacturer Medtronic agreed to pay the US government \$8.1 million to resolve allegations that it violated the FCA by paying kickbacks to induce a South Dakota neurosurgeon to use certain Medtronic products.<sup>23</sup> A US DOJ attorney involved in this case stated that 'The quality of medical care is eroded – and patients and their families suffer – when companies and physicians enter into these sorts of under the table schemes to create illegal financial incentives to increase the use of medical devices'.<sup>23</sup> In July 2020, the DOJ announced that Novartis paid over \$642 million to settle allegations of improper payments to patients and physicians.<sup>24</sup>

From 1987, the first fiscal year after the whistle-blower amendment, to 2020, the total government health-related civil fraud recovery by the Department of Justice was \$43.38 billion and, of that amount, \$35.49 billion resulted from whistle-blower lawsuits filed under the FCA. Put another way, 82% of healthcare civil fraud recoveries have resulted from lawsuits initiated by whistle-blowers. Since 1986, \$5.99 billion has been paid to whistle-blowers as a reward for bringing these actions.<sup>25</sup> Whistle-blowers remain critical in any fight against fraud.

In Europe, however, a 2019 EU Whistleblower Protection Directive urging each member country to enact enhanced whistle-blower legislation by December 2021 is considerably

behind in implementation. A recent report stated, 'By mid-February 2021, two-thirds (18) of the 27 member states had not started or had made minimal progress in the transposition process, and it is uncertain whether any EU country will transpose the Directive by the December deadline'.<sup>26</sup> In the UK, legislation is in place to provide protection for whistle-blowers, but it is not aligned with the EU directive, which 'significantly advances whistleblower protection and raises the bar higher than most existing legislation, such as the UK's Public Interest Disclosure Act'.<sup>27</sup>

## Conclusion

The US government-mandated open payments law created a comprehensive, publicly available database of payments made by drug and medical device companies to physicians (and teaching hospitals). This provides previously unavailable comparisons with voluntarily submitted conflict of interest information from the same health professionals to medical journals. Additionally, a rapidly increasing number of studies, published during 8 years since open payments began, have demonstrated the deleterious effects of such judgement-affecting financial conflict of interest on patient treatment decisions. Unfortunately, the UK as well as many European countries lack laws mandating such disclosure. Mandatory disclosure, though not sufficient in itself, can pave the way for other necessary changes.

These include more scrutiny by patients and physicians of the details of open payments to hundreds of thousands of physicians. Additionally, medical journals and academic medicine, more broadly, can use this complete information for better guidance on scrutinising authors for publication bias and for background checks on current or prospective faculty.

Given the rapid increase in successful whistle-blower-derived DOJ litigation since 1986, access to the OPD has helped DOJ lawyers and non-government lawyers representing whistle-blowers build meritorious fraud cases against pharmaceutical and device manufacturers. Reducing, as much as possible, such physician financial conflict of interest moves the quality of healthcare towards what is best for patients, not for pharmaceutical and device manufacturers. As is the case with mandatory public disclosure legislation, Europe and the UK are similarly lacking adequate whistle-blower protection legislation, the purpose of which is to enhance the enforcement of laws, thus preventing loss or harm. Personal payments from industry reduce the ability of physicians to make independent therapeutic decisions that may be harmful to patients,

strongly arguing for an end to such payments. Since whistle-blower protection is critical to any fight against fraud, much of which is in the health area, further enforcing strong US laws and strengthening whistle-blower protections in Europe, the UK and elsewhere are urgently needed.

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