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Decoding disclosure: Comparing conflict of interest policy among the United States, France, and Australia☆

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ABSTRACT

"Sunshine" policy, aimed at making financial ties between health professionals and industry publicly transparent, has recently gone global. Given that transparency is not the sole means of managing conflict of interest, and is unlikely to be effective on its own, it is important to understand why disclosure has emerged as a predominant public policy solution, and what the effects of this focus on transparency might be. We used Carol Bacchi's problem-questioning approach to policy analysis to compare the Sunshine policies in three different jurisdictions, the United States, France and Australia. We found that transparency had emerged as a solution to several different problems including misuse of tax dollars, patient safety and public trust. Despite these differences in the origins of disclosure policies, all were underpinned by the questionable assumption that informed consumers could address conflicts of interest. We conclude that, while transparency reports have provided an unprecedented opportunity to understand the reach of industry within healthcare, policymakers should build upon these insights and begin to develop policy solutions that address systemic commercial influence.

1. Introduction

"Let a little bit of sunshine into this world of financial relationships – it is, after all, the best disinfectant" were United States (US) Senator Grassley's words to the Senate in 2007 when he first introduced the Physician Payments Sunshine Act, which would mandate public disclosure of payments to physicians from pharmaceutical and medical device companies [1]. The Sunshine Act became law in the US in 2010, and "sunshine" has subsequently gone "global [2]," with numerous other countries, including France, Slovenia, Turkey, Australia and Japan, either adopting, or contemplating, "sunshine-like" legislation, government regulation, or industry self-regulation.

These initiatives have emerged as a result of increasing concern about the influence of health-related industries over the decisions of health professionals, and associated conflicts of interest [3]. Payments from pharmaceutical companies to physicians have garnered particular attention because these relationships have been associated with, for example, increased prescribing frequency and cost, greater awareness of, preference for and rapid prescribing of new drugs, decreased prescription of generic drugs, and formulary addition requests for promoted drugs [4–6]. This suggests that receipt of payments and gifts may be contributing to escalating healthcare costs and threats to public safety as brand name, heavily marketed medications are more likely to be recalled for safety reasons or carry black box warnings, as was the case with Vioxx [7].

Supporters of 'sunshine' policies, like US Senator Grassley, advocate for *public* reporting of health professionals' financial ties to industry as a means of managing industry influence and conflicts of interest. Some argue that such reporting empowers those who may be affected by biased decision making [1]. Others hope that public reporting will serve as a deterrent to inappropriate relationships between health professionals and industry, allowing beneficial relationships to continue with the public's knowledge and trust

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[8]. The pharmaceutical industry has been ambivalent about such measures, but has publicly argued that transparency itself will build trust by "neutrali[zing] the charge of conflict of interest [9]."

While these arguments for public disclosure are compelling, transparency is not the only way of managing conflicts of interest arising from relationships between health professionals and industry [3,10]. Other options include prohibiting certain relationships between health professionals and industry such as the receipt of gifts or commercial sponsorship of continuing medical education [11,12], banning pharmaceutical industry representatives and drug samples from clinical settings [13], strengthening regulatory structures and promoting independence from industry [10,14,15], and putting in place processes to guide and manage the conduct of individuals with conflicts of interest [16]. Disclosure also has limitations as a strategy for managing conflicts of interest including promoting a view among health professionals that "anything goes" once conflicts have been declared ("moral licencing"); leading patients to believe that a doctor must be trustworthy simply because he or she has been open; and creating pressure on consumers to comply with whatever advice might follow from a declaration of a conflict due to a fear of signalling distrust [17,18].

Given that transparency is not the sole means of managing conflict of interest, and may even be counter-productive when used on its own, it is important to understand why disclosure has emerged as a predominant public policy solution, and what the effects of this focus on transparency might be.

1.1. Theoretical framework

One approach to answering such questions is offered by policy theory scholar Carol Bacchi who suggests that policy trends of this kind can be understood by asking: what is the nature of the *problem* that a particularly policy—in this case transparency regulation—seeks to solve? In contrast to conventional understandings of public policy in which policymakers are seen as reacting to social problems that exist beyond the policy process, Bacchi's post-structuralist approach is premised on the understanding that policy solutions are constitutive of particular definitions of social problems [19]. According to this formulation, policies not only reflect or describe a social reality, but are also normative interventions declaring that something is wrong *in a particular way* and that *a particular kind of* change is necessary. In other words, they are creative and productive efforts that shape particular understandings of problems and that have real consequences for how stakeholders are affected and think about themselves. For example, providing tax credits to families with children under 5 suggests that access to quality childcare is a problem of *affordability*, whereas requiring employers to provide parents with flexible working arrangements suggests it is a problem of the *workplace*. Importantly, the nature of a social problem is rarely officially declared or explicitly stated [20].

Rather than focusing only on whether proposed solutions (e.g. disclosure) solve particular problems (e.g. conflicts of interest), approaching policy analysis with the question, "What is the problem represented to be?" allows for a critical examination of the way both problems and their corresponding solutions are constituted. This, in turn makes it possible to question the policy solution's underlying assumptions, explore alternative ways of characterising the problem, and challenge the power and governing relations that are taken-for-granted by more instrumental approaches to policy evaluation.

With this framing in mind, we use Bacchi's problem-questioning approach to policy analysis [19] to compare the Sunshine policies in three different jurisdictions, the United States, France and Australia.

2. Methods

2.1. Sampling

Among the OECD countries, 7 have adopted statutory "sunshine"-type regulations: the US, France, Portugal, Greece, Romania, Latvia and Denmark [21]. We chose the US and France as case studies for this comparative analysis because these were among the earliest and most influential examples of sunshine legislation. In numerous other OECD countries, including Australia, Canada, Japan, The Netherlands, and the United Kingdom, some form of public disclosure of financial relationships between health professionals and industry occurs through voluntary industry self-regulation. In Australia, however, a specific, mandated form of industry self-regulation arose through direct interaction between a government regulator and an industry trade association (Medicines Australia), thus we selected Australia as the third comparative case study.

2.2. Data sources

Our principal texts for analysis were the primary and most recent sources of the transparency policies in each of the three jurisdictions. In the US, this was the text of the Congressional bill, the "Physician Payments Sunshine Act of 2009"[22] and the proposed rule from the agency responsible for promulgating this bill, the Centers for Medicare and Medicaid Services [23]. In France, this was the Bertrand Law, which came into force in May 2013 as an amendment to the *Public Health Code* [24] and was recently updated in 2017 through further legislation [25]. In Australia, the primary text was the 18th edition of the Medicines Australia Code of Conduct effective May 2015 [26].

We purposively sampled precursor legislation or previous editions of the primary texts and associated documents and media releases noting amendments. We also sampled policies, correspondence, and research that were referenced in the primary texts, for example, the authorisation of the Medicines Australia Code of Conduct by the regulator, the Australian Competition and Consumer Commission.

2.3. Data analysis

We used Bacchi's stepwise analysis to critically interpret the ways that public disclosure (a 'solution') has emerged in response to the problem of conflict of interest [19]. For each policy, we asked:

1. What is the 'problem' represented to be?
2. How has this representation of the 'problem' come about?
3. What presuppositions or assumptions underlie this representation of the 'problem'?
4. What is left unproblematic in this problem representation? Can the 'problem' be thought about differently?
5. What effects are produced by this representation of the 'problem'?
6. How/where has this representation of the 'problem' been produced, disseminated and defended? How could it be questioned, disrupted and replaced?

We first describe the key features of the US, French and Australian sunshine policies. Then, we use Bacchi's framework to show how a variety of problem constructions underpin otherwise similar policy approaches. We then critique the key assumptions inherent in these problem constructions, and conclude by proposing an alternative problem representation and policy recommendations.

Table 1
Key characteristics of sunshine policies in the United States, France and Australia.

Characteristic	United States Physician Payments Sunshine Act	France Bertrand Law	Medicines Australia Code of Conduct, 18th Edition
Date of database implementation	August 1, 2013	June 26, 2014	July 1, 2007
Responsible agency	Centers for Medicare & Medicaid Services (CMS)	Ministry of Social Affairs and Health	Medicines Australia, industry trade association
Type of policy	Federal legislation, Section 6002 of the *Affordable Care Act*	National legislation, *Public Health Code*	Industry self-regulation (with mandated disclosure for member companies)
Target industries	Manufacturers of drugs, medical devices, biologics, and medical supplies covered by federal health insurance programs	Manufacturers of drugs, medical devices, biologics, medical supplies, cosmetics, contraceptives, biomaterials, biology test products, contact lenses, health software, additional "therapeutic products"	Manufacturers of prescription drugs
Payment recipients covered	Physicians (doctors of medicine, osteopathy, chiropractic medicine, dentistry, podiatry, optometry) Teaching hospitals Group purchasing organizations	Health professionals (physicians, nurses, pharmacists, midwives, dieticians, medical interns and students) health entities (professional and patient organizations, health publishing and software companies, and companies providing health professional training)	Health professionals registered to practice in Australia who may prescribe, dispense, recommend, supply or administer a prescription medicine in Australia
Type of payments covered	Cash Cash equivalent In-kind items or services Stock, stock options, ownership interests, dividends, profits, returns on investments (totaling > USD$10 or > USD$100 per year)	Transfers of value over €1.00	Payments or transfers of value
Nature of payments covered	Consulting fees Other service fees Honoraria Gifts Entertainment Food and beverage Travel and lodging Education Research Charitable contribution Royalties or licenses Ownership or investment interests Speakers' fees Grants	Agreements (including the purchase of goods or services)	Speakers' fees Sponsorship to attend educational event (airfare, accommodation, registration fees) Consulting fees Advisory Board membership fees (sitting fees, airfare, accommodation) Market research participation fees Sponsorship of third party educational meetings and symposia Health consumer organisation support
Payments not covered	Transfers of value under USD$10 Combined total of annual transfers of value under USD$100 Product samples for patient use Patient education materials		Food and beverage expenditure (<AUD$120) Consulting fees related to research and development
Format of disclosure	*Open Payments*, searchable, public web database	*Transparence Santé*, searchable, public web database	Searchable table on company website and CSV file available for download Hyperlink to company report on Medicines Australia website
Sanctions	Failure to report: Up to US$10,000 per violation Known failure to report: Up to US$100,000 per violation Cap of US$1,150,00	Deliberate omission (individuals): €45,000 Deliberate omission (company): €225,000 Additional sanctions, such as suspension of business activities or closing of facilities	Order to cease or withdraw promotional activity Publicised failure to comply Complaint forwarded to ACCC or TGA Suspension or expulsion of membership Monetary fines up to $300,000 per complaint

3. Results

3.1. Nature and scope of sunshine policies

Sunshine policies in the US, France and Australia all share the aim of making the ties between individual health professionals and health-related industries such as pharmaceutical, medical device or biological manufacturers publicly transparent. Table 1 provides an overview of key characteristics of these sunshine policies. All sunshine policies focus on reporting ties of a quantifiable nature between companies and individuals, and most commonly, the monetary value of such interactions. The information is then made publicly available online in a variety of formats. Within these broad parameters, there are variations across jurisdictions, especially with regard to the type of transfers of value reported, the recipients whose payments must be accounted for, the manufacturers bound by the policy, and the format in which they are rendered to the public.

In the US, the Physician Payments Sunshine Act is a federal legislation that requires manufacturers of drugs, medical devices, biologicals, and medical supplies covered by federal health insurance programs to disclose transfers of value rendered to physicians and teaching hospitals [22]. The legislation covers a broad range of payments to physicians and teaching hospitals, valued at over US$10, or totaling more than US$100 in one calendar year. However, it excludes product samples that are intended for patient use, as well as educational materials that are intended to directly benefit the patient. Physicians are defined as doctors of medicine, osteopathy, dentistry, dental surgery, podiatry, optometry, and chiropractic medicine. This information is publicly available through the *Open Payments* website, which is managed by the Centers for Medicaid and Medicare Services (CMS) [23]. The website offers a consumer-facing search interface that allows the search for payments by individual physician, teaching hospital or company. CMS also provides files of summary data for download in analysable format. Concerns about the omission of non-physician health professionals, such as nurses, pharmacists, nurse practitioners and physician assistants in the legislation has led to the recent drafting of the Provider Payment Sunshine Bill, which would extend the Sunshine Act provisions to all non-physician prescribers [27].

Table 2
Problem representations underpinning public disclosure policies in the United States, France and Australia.

Country	Problem representation	Illustrative examples
United States	Protecting the health care consumer • Addressing healthcare costs • Responsible use of tax payer dollars • Informed choice • Patient safety	"Increased transparency regarding the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers will permit patients to make better informed decisions when choosing health care professionals and making treatment decisions, and deter inappropriate financial relationships which can sometimes lead to increased health care costs." – Centers for Medicare and Medicaid final rule on Physician Payments Sunshine Act [23] "This bill will shine a much needed ray of sunlight on a situation that contributes to the exorbitant cost of health care. Patients have the right to know if drug and device makers are attempting to influence physician prescribing decisions with gifts, consultations and travel." – Quotation from US Senator Chuck Schumer upon introduction of the Physician Payments Sunshine Act [1] "'That was the whole hook,' Thacker recalls. 'You tie in NIH [National Institutes of Health] money, that's when a senator can come forward and say: 'Hey look, you're taking taxpayer dollars'." – Staffer Paul Thacker on rationalizing US Senator Grassley's involvement in the issue of conflicts of interest in medicine [31] "It's important to shed light on the millions of dollars these companies spend on marketing – money that could be put into research or lowering the cost of prescriptions." – Quotation from US Senator Klobuchar endorsing the Physician Payments Sunshine Act [32] Precedence in Anti-Kickback legislation [33] "Such payments [from industry] could encourage psychiatrists to use drugs in ways that endanger patients' physical health, said Dr. Steven E. Hyman, the provost of Harvard University and former director of the National Institute of Mental Health. The growing use of atypicals in children is the most troubling example of this, Dr. Hyman said." – From a *New York Times* expose on side effects in children taking antipsychotic drugs that was the impetus for Thacker and Grassley's investigation [34]
France[a]	Threats to trust in the healthcare system and regulator • Patient safety • Conflicts of interest between health authorities and pharmaceutical companies	"In other sectors of public health and safety, the precautionary principle protects the patient. In [the pharmaceutical] sector, based on our investigations into the MEDIATOR® files, doubt gave way to a propensity to keep the drug on the market. Might this tendency, different from all other public health sectors, be due to the close interaction between the experts and the pharmaceutical companies? The question bears further investigation." – From the report on the inquest into the drug MEDIATOR® [35] "Restoring public trust requires the implementation of a clear provision providing solid guarantees. . .it is time to implement a single database, complete and coherent, of Public Declarations of Interest. . .regardless of the role of the expert in question. The management of public declarations of interest must be centralized under one body." – From the national drug foundation working group synthesis report [36] "Article L. 1453-1 of the Public Health Code, introduced by Article 2 of the 2011–2012 Law of 29 December 2011, aims to ensure complete transparency and improve public information regarding ties between, on the one hand, companies producing health and cosmetic products. . . and on the other, various intervening actors in healthcare, especially health professionals" – Instruction from the Direction Générale de la Santé to the Ministère des affaires sociales et de la santé [37] ". . .[a]nother source, who declined to be identified, is worried that public confidence in the French health system is being seriously shaken after having recovered from a contaminated blood scandal 25 years ago. The solution then was to create a public health administration, which currently compares well with others in Europe; but to restore public confidence now, 'we will have to look for solutions elsewhere, which will be more complicated'" – Quotation from *Lancet* article "Drug scandals in France: have the lessons been learnt?" [38]
Australia	Threats to trust in the pharmaceutical industry • Preventing discredit to the pharmaceutical industry • Ensuring public confidence in the pharmaceutical industry • Keeping up with international standards	"Companies may choose to support, initiate or become involved in activities with healthcare professionals. Such involvement either by financial or other means must be able to successfully withstand public and professional scrutiny, and conform to professional and community standards of ethics and good taste" – From the Medicines Australia Code of Conduct [26] "Interactions with healthcare professionals must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry." – From the Medicines Australia Code of Conduct [26] "Medicines Australia chief executive Tim James said the code would improve transparency and increase patient confidence that the relationship between the pharmaceutical industry and healthcare professionals was appropriate. 'The code shows the leadership and integrity of the Australian pharmaceutical industry,' Mr James said." – As reported in the *Sydney Morning Herald* [39] "Improving transparency around payments to individual doctors will play an important role in promoting community confidence in the integrity of these payments to healthcare professionals." – Quotation from ACCC Commissioner upon granting conditional approval of Medicines Australia 17th ed of the Code of Conduct [40] "We also call on Australia's elected representatives to consider introducing legislation similar to the Sunshine Act, to bring Australia into line with international benchmarks on transparency in healthcare." – Preamble to petition from healthcare activists [41]

[a] Illustrative quotations originally in French were translated to English by Roojin Habibi.

In France, the Bertrand Law, which was entered into force in May 2013 as an amendment to the *Public Health Code* [24] requires that payments to health professionals and health entities be accessible on the government website *Transparence-Sante* [25]. Although initially inspired by the US, France's legislation is broader in scope in terms of professionals and products covered as well as the threshold for disclosure. Under these provisions, any direct or indirect transfers of value over €1 to health professionals, including physicians, nurses, pharmacists, midwives, dieticians, medical interns and students, as well as health entities, including professional and patient organizations, and health education, publishing and software companies, must be reported. A wider range of health-related industries fall under the purview of the French sunshine policy, including manufacturers of cosmetics and contraceptives.

In Australia, the pharmaceutical industry is governed mainly through self-regulation overseen by Medicines Australia, the national trade association for manufacturers of prescription medicines. Transparency provisions are set out in Medicines Australia's Code of Conduct for ethical marketing and promotion [26]. The Code of Conduct, including the transparency provisions, is enforced for member companies, although membership in Medicines Australia is voluntary and these provisions do not apply to non-member pharmaceutical companies operating in Australia, nor to manufacturers of over-the-counter or generic medicines. While the Medicines Australia Code is a form of industry self-regulation, it is under the oversight of the Australian Competition and Consumer Commission (ACCC), whose responsibility is to ensure that businesses and individuals comply with competition, fair trading, and consumer protection laws [28]. In exchange for safe harbour provisions under anti-competition legislation, the ACCC reviews and grants Medicines Australia conditional approval of the Code of Conduct for up to five-year periods [28].

Australia was one of the first countries to introduce transparency policies related to pharmaceutical company payments to health professionals in 2007, however, payments were reported in aggregate and made public in PDF format [29]. Further transparency provisions have been included as part of the 18th edition of the industry's Code of Conduct for ethical marketing and promotion, which requires reporting of transfers of value to individual health professionals in analysable format on individual company websites [26]. Under the Code, Medicines Australia member companies are required to report transfers of value related to prescription medicines, including payments for consulting or advisory board membership, sponsorship to attend an educational event including travel, and speaker honoraria and travel support. Health professionals covered under this reporting include any registered health professional "who in the course of their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine in Australia." [26] Notable omissions include the receipt of food or beverages, which were deemed "secondary" to other transfers of value and because the Code already stipulates a $120 spending threshold per person per meal [26]. Authorization of this revision of the Code has been granted by the ACCC on condition that Medicines Australia takes reasonable measures to develop and implement a Central Reporting System where transfers of value to individual health professionals would be made both visible and in an analysable format in a centralized repository.[28] Since 2015, Medicines Australia's Centralised Database Working Group has been investigating the feasibility of implementing a central reporting database in order to comply with the mandate [30].

3.2. Problem representations and how they came about

The public discourse around the introduction of transparency policies in the US, France and Australia characterised a range of problems to which public disclosure of financial ties between health professionals and industry was the proposed solution. Table 2 provides illustrative examples of this range of problem representations across the three countries. In response to Bacchi's first and second questions, "what is the problem represented to be?" and "how did it come about?" we describe the dominant problem representations below and provide a narrative analysis of how these particular problem representations came about.

3.2.1. Protecting the healthcare consumer: the United States

In the US, transparency initiatives have tended to be justified as a means to ensure the ethical and rational spending of taxpayer dollars. Scrutiny of financial ties between physicians and drug manufacturers has a long history in the US in the form of the federal Anti-Kickback Statute as well as being under the purview of the Office of the Inspector General [33]. These policies ensure that relationships between physicians and industry do not result in inducements that could result in preferential referral or recommendation of products or services covered by federal health care programs. Several states, including Maine, Massachusetts, Vermont and Minnesota experimented with public disclosure laws as early as the 1990s [42]. Public reporting of physicians' financial ties was also spearheaded by ProPublica, a team of investigative journalists who, in 2010, established a publicly searchable payments database, Dollars for Docs. Initially, the data were compiled using reports disclosed through legal settlements between certain companies and the federal government [43].

The Physician Payments Sunshine Act was formally introduced in 2007 by US Senator Charles Grassley, with co-sponsorship from Senator Herb Kohl [44]. As a senior member of the Senate Finance Committee, Senator Grassley justified the need for a transition from *ad hoc* public reporting to a systematic and federal initiative primarily on the basis that public reporting of financial ties between physicians and industry would shed light on influential relationships that contribute to the "exorbitant cost of healthcare" and misuse of public dollars [1,31]. To bolster their case for the need for greater protection of healthcare consumers, Grassley and Paul Thacker, an journalist, investigated the financial disclosures of academic physicians receiving grants from the federally-funded National Institutes of Health (NIH). Under federal rules, NIH grant recipients are required to disclose to their universities financial interests of more than $10,000 in cash or 5% equity in a company. Between 2007 and 2008, Grassley and Thacker's audits of the mandatory disclosures of academic physicians revealed that over 50 researchers affiliated with more than 30 universities had failed to disclose sums as high as $800,000 in payments received from industry [31]. Possibly as a result of the substantial negative publicity generated as a result of these investigations, pharmaceutical companies began to publicly accede that transparency was required, pending revisions of the proposed bill [45]. The bill was eventually endorsed by the American Medical Association, Pharmaceutical Research and Manufacturers of America, and the American Academy of Family Physicians, among others [32]. It garnered further momentum when President Obama placed the Senate Finance Committee in charge of drafting the 2010 Patient Care and Affordable Care Act, which included the Sunshine Act as an amendment.

With its roots in anti-kickback policies and through direct consultation with the Inspector General, the final rule of the Physician Payments Sunshine Act explicitly acknowledged that payments from manufacturers to physicians could influence decision-making in ways that could compromise patient care and "lead to increased health care costs "[23]. Though recognizing that disclosure alone will not differentiate between beneficial and problematic relationships, transparency was promoted as a solution to the problem of threats to consumer protection by bolstering "better informed decisions" on part of healthcare consumers [23].

3.2.2. Rebuilding public trust in the health care system: France

In contrast to the US, where the Sunshine Act evolved gradually out of a series of strategic investigations into the (mis)use of taxpayer dollars, France's Sunshine legislation emerged suddenly in 2011 in the aftermath of a public health crisis that profoundly destabilized public trust in the French drug regulation system. The French law was therefore framed as a policy response to an explicit and urgent deficiency of trustworthiness in the health care system.

In the late 1990s, discoveries about the cardiotoxic properties of fenfluramines (appetite suppressants used to manage obesity-related conditions) led to their withdrawal from drug markets worldwide. However, one of these drugs, benfluorex (Mediator®), approved in France to control diabetes-related lipid levels, continued to be marketed and prescribed to patients, especially patients with weight concerns, more than ten years after the purge of fenfluramines in other countries [46]. During this time, the drug's manufacturer, Servier, engaged in off-label marketing of the drug for weight loss [35]. By the time the drug was withdrawn from the French market in 2009, an estimated 500–2000 deaths had been linked to its use, mostly in an off-label context [46,47].

The slow response of regulators and health professionals provoked a sudden wave of public and media scorn. Investigations into how benfluorex managed to penetrate and stay on the French market for so long quickly led to inconvenient truths about the extent of conflicts of interest in the French healthcare system [48]. As an indication of the shockwaves sent through the health community, the head of the drug regulatory agency stepped down, and the French pharmaceutical industry association 'LEEM' ousted Servier from their membership [48].

The response of then-Health Minister Xavier Bertrand was rapid, as he convened public consultations with over 350 stakeholders including representatives of industry, health professionals, educators, regulators, politicians and consumer groups [36]. Inspired in part by the recent success of the Physician Payments Sunshine Act in the United States, one of the recommendations emerging from stakeholder consultations was to codify an obligation on health-related industries to report financial ties to health professionals [36].

In 2012, this obligation became law with article 2 of the Bertrand Law, now codified as article L. 1453-1 of the *Public Health Code*, which mandated the establishment of a public database documenting health professionals' ties to medically-related industries [24]. In a speech to the Senate, the Health Minister explained that the primary goal of the law reform was to ward off conflicts of interest and promote the transparency of decisions in healthcare [49].

Despite these promises, a number of loopholes remained from the way that legislators interpreted the Bertrand Law [50]: of most significance, contracts between industry and health professionals for work or services provided, including the monetary value of the resulting remunerations or fees, was excluded from reporting requirements [51]. In 2015, this issue was brought before the Council of State, which voted unanimously in favour of abolishing previous restrictions on disclosed information [52]. By the end of 2016, a new decree was issued, reflecting this decision and requiring additional reporting, which includes the type of relationship, the monetary value of the payment (if over €10), the precise subject matter of the contract, and details of all beneficiaries [25]. These changes came into effect in July 2017.

Despite significant efforts to reform the French sunshine law, critics argue that the post-benfluorex era has been primarily focused on conflicts of interest between health professionals and the industry, neglecting the fact that the drug regulatory agency and other public officials were equally found to have failed to address the evidence pointing the drug toxicity [35]. In the words of Bernard Debré, physician and Member of Parliament, " [c]onflict of interest remains rife [and] the pharmaceutical lobby is as powerful as ever" [38].

3.2.3. Preserving the public image of the pharmaceutical industry: Australia

In 2007, Australia became one of the first countries to introduce transparency policies related to pharmaceutical company payments to health professionals, allowing then chief executive of the pharmaceutical industry trade association, Medicines Australia, to claim "The Australian pharmaceutical industry is now the global leader in terms of transparency and accountability" [53]. This statement reflects the dominant problem representation underpinning transparency initiatives in Australia, which focuses on preserving the public image of the pharmaceutical industry and keeping up with international policy efforts. Explaining that, "[n]o one knows more about pharmaceuticals than the people who make them," then chief executive of Medicines Australia Ian Chalmers publicized, "I hope the publication of this report gives the community a better sense of the contribution the pharmaceutical industry makes to our healthcare system by saving, improving or prolonging the lives of Australians"[53].

Despite these claims of global leadership on the part of the pharmaceutical industry, payments to health professionals were first reported in aggregate and made public in PDF format by individual companies, making it difficult to search, conduct analyses or detect patterns across companies [29]. Spurred by the debates about the 2007 Sunshine bill in the US, stakeholders began to call for similar policy in Australia, and the Australian Competition and Consumer Commission (ACCC) critiqued the lack of transparency provisions in the then 16th edition of Medicines Australia's Code of Conduct [54]. In 2013, subsequent to the passing of the United States Sunshine Act, the ACCC approved Medicines Australia's 17th edition of their Code for only two years instead of the standard five, with the directive to improve transparency of payments and sponsorship made by pharmaceutical companies to individual healthcare professionals [40]. Over 450 health researchers and practitioners also signed a petition for the ACCC to introduce some form of sunshine policy in Australia [41]. The regulator again framed the problem as one of threats to public trust in the industry, explaining, "Improving transparency around payments to individual doctors will play an important role in promoting community confidence in the integrity of these payments to healthcare professionals "[40].

In 2015, new transparency provisions were delivered in the 18th Edition of the Medicines Australia Code of Conduct, which require reporting of transfers of value to individual health professionals in analysable format (i.e. CSV files) on individual company websites [26]. The ACCC granted authorization of the most recent revision of the Code on condition that Medicines Australia takes reasonable measures to develop and implement a Central Reporting System where transfers of value to individual health professionals will be made both visible and in an analysable format in a centralized repository [28].

While Medicines Australia publicly endorsed its new transparency rules, the idea of publicly disclosing financial ties between health professionals and industry seemed to hold little appeal for Medicines Australia at the outset. In a speech to an Australian professional development conference in Sydney in 2012, then-President Brendan Shaw imparted his fear thatIf medicines companies were to just start publishing the names of doctors and the amounts of sponsorship without any bedrock of understanding of the importance of that work, the resulting commentary would border on a witch hunt. . .it would make the Spanish Inquisition look like a Sunday church picnic [55].

The industry organisation was not alone in this stance. The Australian Medical Association also cautioned the ACCC against including sweeping transparency provisions in the Code [56]. How-

ever, over 450 health professionals advocated for public disclosure, signing a petition that called on Australia to keep up with "international benchmarks on transparency in healthcare," providing the ACCC with a legitimating voice from within the medical profession [41]. By June 2013, likely owing to the pressure imposed by the ACCC and advocate groups, Medicines Australia's stance changed in favour of transparency. This time, Shaw boasted about the body's new transparency model, recognizing that while "[industry] engagement with doctors [was] important and legitimate because patients want to be sure that their doctors know how to use the medicines they're being prescribed," transparency about this engagement would build "public trust and confidence in those relationships"[57]. Australia's move towards public disclosure of industry ties thus seems to be have been driven primarily by a desire to remain in compliance with the regulator, but has also been treated as a public relations opportunity to instill trust in the industry.

4. Discussion

4.1. Underlying assumptions, silences, and effects

Our application of Steps 1 and 2 of Bacchi's framework illustrates that a variety of problem constructions underpin otherwise similar policy approaches, focused on public disclosure of industry interactions (Table 2). Though each jurisdiction presented multiple and sometimes overlapping problem representations, we identified a dominant problem framing that was specific to each context. In the US, the problem was largely characterised as a matter of consumer protection and the misuse of taxpayer dollars. In France, it was characterised as an issue of patient safety, the trustworthiness of the medical profession and the adequacy of regulatory systems. And in Australia, it was characterised primarily as a lack of openness and accountability on the part of the prescription medicines industry, and as a failure of Australian regulators to keep up with international benchmarks. However, despite the variation in problem representations each manifest problem (or set of problems) has been implicitly assumed to stem from a common underlying problem – a lack of transparency. As such, disclosure has emerged as the proposed solution in all three jurisdictions.

It may be that lack of transparency does, in fact, contribute to each of the manifest problems outlined above, and that disclosure could be an important means of addressing them. However, the exclusive focus on a lack of transparency as the "core" problem, and disclosure as the key solution, reveals a shared set of broader assumptions, not only about conflicts of interest and their management, but also about healthcare and its relationship to industry, and about healthcare systems, markets and professions more generally. In order to explore and critique these assumptions, we now turn to Bacchi's third question: "What presuppositions or assumptions underlie this representation of the 'problem'?" and her fourth question "What is left unproblematic in this problem representation?" We then reflect on the effects of these assumptions and silences for patients and the public at large (question five).

The most obvious presupposition underpinning the three disclosure policies is that lack of transparency is the primary cause of a wide variety of problems (waste of taxpayer dollars, regulatory failure, and lack of industry accountability) and, correspondingly, that disclosure is a necessary and sufficient means of managing these problems. As we explained earlier, there are a number of problems with the assumption that disclosure is, on its own, a satisfactory approach to managing conflict of interest [17]. Given that we know that disclosure can have paradoxical effects on professional and industry behaviour, it seems naïve to assume that disclosure would, on its own, ensure that tax dollars are not wasted (US), patients' safety is secured (France), and trust in the pharmaceutical industry is maintained (Australia). Our skepticism is buttressed by the fact that none of the sunshine policies that we analysed articulated exactly *how* public disclosure is meant to solve whatever the manifest problem might be. For example, the final rule for the US Physician Payments Sunshine Act explains that increased transparency will "deter inappropriate financial relationships which can sometimes lead to increased health care costs" without identifying which financial relationships are considered "inappropriate" or placing any limits on the same [23]. Similarly, even in France, where the concern was over public safety, and the sunshine policy was supported by a variety of government-consulted stakeholder groups, proponents of the policy have provided few details on precisely how disclosure of payments rendered to health professionals might help to avoid a similar public health crisis in the future. Rather, as evidenced by the shifting public stance of the Australian pharmaceutical industry towards transparency mandates, disclosure seems to have emerged as a palatable political solution that allows governments to appear responsive to public concerns and health-related industries to appear credible and compliant while avoiding actual regulation of their marketing activities.To the extent that the policies we analysed do refer to their supposed mechanism of action, this is limited to vague references to the role of disclosure in promoting consumer choice – the idea apparently being that information will empower the average healthcare consumer to choose his or her healthcare provider, and thereby send a signal to the market that unethical, biased or compromised practices will be commercially unviable. This mechanism was framed by US Senator Kohl as a "win-win" for consumers, explaining, the pharmaceutical industry told the Aging Committee that they believe their practices are above-board. If that is the case, full disclosure will only serve to prove them right. If that is not the case, full disclosure will bring their influence-peddling out from the shadows. Either way, patients win [1].

All three sunshine policies therefore, seem to be premised on the principle of *caveat emptor*, where the burden of responsibility for assessing the adverse outcomes of conflict of interest is shifted to those on the receiving end of healthcare [58]. This is, however, problematic partly because, as discussed above, patients may not be able to interpret disclosures and partly because they may not be able to act on the knowledge they have. In this regard, it is noteworthy that although a recent systematic review [59] and randomized controlled trial [60] found that receipt of payments may be associated with decreased public trust in physicians, patients are rarely in a position to seek an unconflicted second opinion or to reject their primary physician's advice due to a fear of signalling distrust [18,61].

4.2. How could the problem and its solution be thought about differently?

If we accept that the current rationale for public disclosure is underpinned by problematic assumptions about both the cause of the problem (lack of transparency) and the solution (disclosure), then this leads us to Bacchi's final question, which asks how the problem representation could be disrupted and replaced.

We believe that the answer to this question lies in reframing the problem of conflict of interest so that it is seen not solely or even primarily as one of lack of transparency, but rather as one of excessive dependence of biomedicine on health-related industries. This, in turn, has major implications for the management of conflict of interest, for If the problem is represented as a problem of independence rather than transparency, then this suggests the need for systemic, structural reforms to address industry influence within healthcare.

Table 3
An alternative problem representation and policy solutions for conflicts of interest in healthcare.

Problem representation	Key assumptions	Policy solutions
Lack of transparency	Informed consumers can differentiate between appropriate and inappropriate relationships between health professionals and industry	Public reporting of specific financial relationships between health professionals and medically-related industry
	Public scrutiny will act as a deterrent to inappropriate financial relationships	Focus on prescribers and prescribing decisions as a quantifiable measure of industry influence
	Inappropriate relationships have the potential to influence individual healthcare decision-making	Report payments to identified individuals Create public-facing, searchable interface for healthcare consumers
Lack of independence	A power differential exists between patients and health professionals	Prohibit certain marketing activities targeted at health professionals such as the provision of gifts, entertainment, food and beverage
	Commercial influence is systemic	Prohibit sales representatives from accessing clinical spaces
	Commercial influence affects individual health professionals even if they eschew financial relationships with industry	Ensure the financial and advisory independence of healthcare regulators

While this would not be easy, greater independence could be achieved by an increased investment of public funds in research and development of new medicines thereby reducing reliance on industry or pooling of industry research funds so that they are entirely in the control of public researchers; ensuring that health professional training programs are free from commercial influence; and the establishment of an independent body to conduct continuing medical education of health professionals [3,14,15].

In this regard, it is noteworthy that the discourse surrounding the sunshine policies in all three jurisdictions we analysed seemed to imply that, simply by "letting the light in," regulators have performed their required duty when it comes to managing conflict of interest. Consequently, there has been relative silence on the need to manage (rather than simply make transparent) interactions between industry and the health professions. Although each of the jurisdictions we analysed has anti-bribery or anti-kickback legislation, this legislation is rarely applied to the routine interactions between health professionals and industry that are captured by transparency reports. And while policymakers would seem to be well-justified if they decided to prohibit the kinds of payments or gifts that are known to be associated with negative prescribing outcomes [4–6], none of the three sample jurisdictions, or any others to our knowledge, have taken this policy step. Table 3 presents an alternative problem representation for conflicts of interest and ensuing policy solutions.

If this alternative problem representation (dependence vs. lack of transparency) is accepted, then the question becomes: what, if any, role do disclosure policies have in the management of conflict of interest? We believe that these policies serve a crucial role by making it possible to systematically document and therefore render susceptible to research and structural intervention the impact of financial ties on healthcare practices and health outcomes. For example, it was disclosure that made possible the analysis that showed that even modest payments, such as a $20 meal, are significantly associated with increased prescription of brand-name drugs [5], – a finding that can now be used to build a case for more definitive policy action.

The potential for a symbiotic relationship between disclosure and management of conflict of interest is evident in Australia where a regulator, the Australian Competition and Consumer Commission (ACCC) – oversees the industry trade association that implements public disclosure. The ACCC enforces competition law, but also fair trading and key consumer protections. Thus, while reinforcing the assumption that disclosure is a form of *caveat emptor* in one sense, in another sense, this regulator is able to oversee multiple facets of marketing by health-related industry that may threaten public health. For example, the ACCC recently took Reckitt Benckiser to court over allegations that the company mislead consumers through marketing specific pain indications for the same over-the-counter medication [62]. The ACCC similarly, took legal action against Pfizer over allegations that the company misused its market position in supplying atorvastatin to pharmacies [63].

Importantly, bringing disclosure policy under the purview of a competition and consumer protection agency positions payments and gifts to health professionals as a marketing strategy and one that is both anti-competitive and potentially harmful to consumers. While Australia is not necessarily ahead of other jurisdictions in terms of reducing dependence on industry and is far behind France and the US in terms of the quality of public transparency reporting, the dual commitments of the ACCC – to both consumer empowerment and protection – shows that a commitment to the former does not necessarily preclude equal commitment to the latter.

4.3. Other lessons from comparisons of sunshine policies

For disclosure to function as an effective tool for guiding structural intervention, it is crucial that disclosures are complete, accessible and analysable. In addition to highlighting the limitations of using public disclosure as the sole or primary means of managing conflict of interest, our comparison among the three jurisdictions highlights several differences among the jurisdictions from which important practical lessons can be drawn in terms of improving the quality and utility of disclosures.

First, the three systems of public disclosure that we analysed differ in terms of the threshold for which disclosure is triggered, with France being the most comprehensive requiring disclosure of any payment over €1. Both the US and Australia, in contrast, set higher thresholds and exclude particular exchanges of value, most notably food and beverage in the Australian context. The justifications given for using high(er) thresholds and for excluding food and beverages is that the alternative would be both excessively burdensome and unnecessary as these exchanges of value are morally insignificant. This provision, however, ignores the fact that small gifts and other transfers of value can have just as much of an influence as larger ones [5,64], and the sustainability of the French system demonstrates that reporting of small gifts and meals is not, in fact, unmanageably burdensome.

Second, there was considerable variation among the three jurisdictions in the types of health professionals that are included in disclosure mandates. In the US, the mandate is restricted to physicians though nurse practitioners, physician assistants and some pharmacists also routinely prescribe treatments. This reveals an assumption that prescribers are the only significant "decision makers" and thus the only group that is susceptible to biases resulting from conflicts of interest [65]. This assumption is, however, not in keeping with what industry appears to know about health care purchasing and clinical decision-making. For example, recent analysis of the Australian transparency reports found that 40% of pharma-

ceutical industry-sponsored events for health professionals had at least one registered nurse in attendance, a category of health professional in Australia currently with only very limited authority to prescribe [66]. The French and Australian policies, in contrast, are much more inclusive, covering any registered health professional that might be involved in patient care or handling of medicines. Notably, the French policy also includes health professional students, thus demonstrating that greater inclusiveness is indeed possible and that conflicts of interest are relevant across professions and career stages.

In this regard, it is noteworthy that all three policies focus their attention solely on health professionals and exclude interactions between industry and non-clinicians such as administrators or researchers or patient advocates, despite the fact that all of these groups may exert a great deal of influence of healthcare decision-making. There is also limited inclusion of collective actors and institutions – teaching hospitals in the US and corporate bodies such as universities or professional associations in France. However, industry has considerable influence over professional associations, academic journals and their publishers, and academic teaching hospitals and universities. There is, therefore, room for improvement in all three policies with respect to the kinds of actors whose relationships with industry are deemed worthy of disclosure.

Finally, our comparative analysis highlighted that the meaning of "transparency" differs among jurisdictions in terms of the types of data and format in which it was made available (Table 1). While all three jurisdictions made ties between health professionals and industry *visible*, the Australian policy did little to assist those who might want to *analyse* these data. Historically, Medicines Australia made their transparency reports available in PDF format, with separate PDFs for each company and reporting period, which precluded comprehensive analysis. One of the ACCC's conditions for approval of Medicine Australia's most recent Code of Conduct was that they would make efforts to provide reports in an analysable format. While the recent reports of individual payments to health professionals are now available in CSV format, they are not provided in aggregate, but instead are located separately on each member company's website. This creates additional barriers to understanding patterns of health professional-industry relationships across companies, or to ascertain whether individual health professionals are receiving payments from multiple companies. Further, Medicines Australia does not provide a searchable database that is consumer-facing. In the US and France, in contrast, have public websites providing search interfaces that enable consumers to look up the payments attributed to individual health professionals, pharmaceutical or medical device companies or other covered entities such as teaching hospitals. These jurisdictions thus provide useful models for ensuring that disclosure is not simply a ceremony, but rather a genuine effort to promote trust and public transparency.

Taken together, these observations illustrate that there is simply no basis for claims that disclosure processes need to be limited with respect to the size and scope of interactions that are included; the individuals and groups whose activities are made visible; or the ways in which data are presented and made available for analysis. The basic tools needed for effective and meaningful transparency exist, and could be instituted by any jurisdiction that was sufficiently motivated.

5. Conclusion

Transparency is an essential part of the solution to conflict of interest because it makes visible the nature and scope of industry influence over healthcare. However, transparency on its own is insufficient in ensuring the independence of health professionals, regulators and health systems. Mapping the emergence of sunshine policies across three different countries and critiquing the assumptions underpinning these policies lays the groundwork for greater critical engagement with transparency policies as a means of addressing conflict of interest. Transparency reports have provided an unprecedented opportunity to understand the reach of medically-related industry within healthcare and particularly, over the decision of health professionals. Policymakers should build upon these insights and use them as the basis for informed policy solutions that address this influence.

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Conflict of interest

The authors have no conflicts of interest to declare.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.healthpol.2018.03.015.

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