Conflicts of interest and industry professional relationships in psychiatric neurosurgery: a comparative literature review

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OBJECTIVE The research required to establish that psychiatric treatments are effective often depends on collaboration between academic clinical researchers and industry. Some of the goals of clinical practice and those of commercial developers of psychiatric therapies overlap, such as developing safe and effective treatments. However, there might also be incompatible goals; physicians aim to provide the best care they can to their patients, whereas the medical industry ultimately aims to develop therapies that are commercially successful. In some cases, however, clinical research may be aiming both at improved patient care and commercial success. It is in these cases that a conflict of interest (COI) arises. The goal of this study was to identify differences and commonalities regarding COIs between 2 kinds of somatic psychiatric interventions: pharmacological and neurosurgical.

METHODS The authors conducted a study focused on professional concerns regarding pharmacological and neurosurgical psychiatric interventions. They used medical and bioethics journal articles as an indicator of professionals' concerns and carried out a thematic content analysis of peer-reviewed articles published between 1960 and 2015, using PubMed and Google Scholar.

RESULTS One hundred thirty-seven relevant articles were identified, of which 86 papers focused primarily on psychopharmacology and 51 on neurosurgery. The intervention most discussed in the psychiatric neurosurgery data set was deep brain stimulation ($n = 42$). While there were no significant differences at the level of categories, pharmacological and neurosurgical interventions differ in the underlying themes discussed. Two issues widely discussed in the articles on pharmaceutical interventions, but largely neglected in the neurosurgery articles, were medical professional issues and industry involvement.

CONCLUSIONS COIs are a neglected issue in the discussion of ethics concerns regarding medical devices in psychiatry. Yet as these interventions become more common, it is important to address them in part through learning from the discussion regarding COIs in the pharmaceutical industry and by developing approaches to address those aspects of COIs that are unique to the medical device industry.

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KEYWORDS conflict of interest; industry; medical device; pharmaceuticals; psychiatry

RESearch and development of psychiatric treatments often depends on collaboration between academic clinical researchers and industry.^{39,41,51} While the 2 parties share the aim of developing safe and effective treatments, they also have additional different aims, which can be in tension with each other. Physicians ultimately aim to provide the best care they can to their patients, whereas

their industry partners ultimately aim to develop therapies that are commercially successful.^{17,35,48,52}

In some cases, however, the physicians' aim may be both improved patient care and commercial success or the development of a scientific reputation. It is in these cases that conflicts of interest (COIs) arise. A COI occurs when professional judgment concerning a primary interest (such

ABBREVIATIONS COI = conflict of interest; DBS = deep brain stimulation; DTC = direct-to-consumer; OCD = obsessive-compulsive disorder.

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as a patient’s welfare or the validity of research) has the potential to be unduly influenced by a secondary interest (such as personal success or financial gain).⁵⁴ This secondary interest need not be illegitimate; however, its influence on professional decision-making can be problematic.

To date, discussion of COIs in psychiatric treatment has been primarily focused on the pharmaceutical industry. In the past decade, however, there has been an increasing interest in research and clinical use of electronic devices in psychiatry, which raises the question of whether and how the use of medical devices may influence physician-industry relationships.

Methods

We conducted a study comparing professional concerns regarding pharmacological and neurosurgical interventions via a systematic literature review of peer-reviewed articles published between 1960 and 2015 using PubMed and Google Scholar. The searches were based on 3 primary types of key terms: 1) intervention terms, 2) psychiatric disorder terms, and 3) ethics terms (Table 1). The study did not require IRB approval, as it did not include research with human subjects.

Articles were excluded if they were deemed to be irrelevant, were not full-length articles, or were unavailable through our university’s library. We used thematic content analysis to identify and analyze patterns (themes) in the data.⁵ Articles were coded iteratively, with themes being developed as coding progressed, to identify major emergent themes. Two authors (L.Y.C. and R.B.) revised an initial set of codes and established a consensus list of codes.³² The unit of analysis was the individual article. We then applied the analytical framework to the full data set.^{5,46}

Two members of the team coded the sources independently. Disagreements were addressed and settled by the entire team. Descriptive statistics were used to characterize the composition and properties of the samples, and the chi-square test was used to test for significant differences.

In this paper, we focus on medical professional issues and industry involvement, 2 themes widely discussed in

articles on pharmaceutical interventions but largely neglected in neurosurgery articles. We coded for medical professional issues in any paper that included discussion of COI, doctor-patient relationship, and professional inertia. Industry-related issues included mention of industry or companies, marketing, lobbying for medical products, or COI (with explicit mention of industry involvement).

Results

One hundred thirty-seven relevant articles were identified, of which 86 papers focused primarily on psychopharmacology and 51 on neurosurgery. The technology most discussed in the psychiatric neurosurgery data set was deep brain stimulation (DBS; n = 42). Advantages of the intervention—in particular, the reversibility and adjustability of DBS—were more frequently mentioned in the neurosurgery articles (64.7%) than in the pharmacological ones (7%). Neurosurgery articles also had more discussion of disadvantages (70.6%) than did articles focusing on pharmaceutical interventions (37.2%). The neurosurgery articles mentioned general risks associated with the intervention as well as more specific disadvantages relating to the invasiveness of the intervention and the fact that they involved direct modification of the brain (the last 2 disadvantages were not even present in the articles focusing on pharmacological interventions, which reflects differences in the interventions themselves). Other important differences were the amount of discussion in the neurosurgery articles regarding lessons from history as well as claims stating that these interventions should be used only as a last resort for cases in which the disorder proves resistant to more common treatment methods and concerns about the vulnerability of patients who may be desperate for treatment (Table 2).

The discussion of medical professional or industry-related issues was more prevalent in the pharmaceutical data set than the neurosurgical one. One-third of articles (34.88%) in the pharmaceutical data set discussed industry-related issues. In the neurosurgery data set, about one-fifth (17.6%) discussed these issues.

Some concerns, despite their distinct frequency, touch on similar issues. For example,

1) Issues of financial ties and improper inducements:

[...] free drug samples; free ‘continuing education’ courses in resort locations, often staffed by teachers associated with the company and sometimes featuring that company’s products. [Pharmaceutical data set]²⁵

[...] corporate relationships, consulting fees, honoraria, research funding and intellectual property rights. [Neurosurgery data set]³⁹

2) Issues of disclosure of COIs and public trust:

Public trust in psychiatrists has been affected by serious accusations of conflicts of interest arising from failure to report such conflicts. [Pharmaceutical data set]⁵¹

The numerous conflicts of interest inherent within this research—especially when undisclosed—could act to undermine the research both by throwing doubt over the legitimacy of the study design and analysis as well as by risking a loss of public trust. [Neurosurgery data set]¹³

TABLE 1. Terms used in search

Intervention Terms	Psychiatric Terms	Ethics Terms
Psychopharmacology	Psychiatric disorder	Ethics
Antidepressants	Obsessive compulsive disorder	Ethical
Antipsychotics	Depression	
Stimulants	Schizophrenia	
	Aggression	
Deep brain stimulation	Anorexia	
Ablative surgery	Anxiety	
Implantable devices	Addiction	
Vagal nerve stimulation	Obesity	
Optogenetics	Dementia	
Psychosurgery	Autism	
	Attention deficit hyperactivity disorder	

TABLE 2. Comparisons between psychopharmacology and neurosurgical intervention literature

Category & Theme	% of Articles That Discussed the Relevant Theme		Value
	Psychopharmacology (86 coded articles)	Neurosurgical (51 coded articles)	
Scientific & technological issues	75.58% (65)	96.07% (49)	
Scientific issues	51.2% (44)	66.7% (34)	
Advantages	7.0% (6)	64.7% (33)	$\chi^2 = 52.39, p = 0.0001^*$
Disadvantages	37.2% (32)	70.6% (36)	$\chi^2 = 14.268, p = 0.0001^*$
Innovation	20.9% (18)	27.5% (14)	
Clinical trial design	51.2% (44)	51% (26)	
Social & political issues	90.69% (78)	84.31% (43)	
Medicalization	27.9% (24)	13.7% (7)	
Social issues	55.8% (48)	52.9% (27)	
Industry-related issues	34.9% (30)	17.6% (9)	$\chi^2 = 4.671, p = 0.031^\dagger$
Media-related issues	4.7% (4)	23.5% (12)	
Medical professional issues	51.2% (44)	31.4% (16)	$\chi^2 = 5.094, p = 0.024^\dagger$
Political issues	41.9% (36)	64.7% (33)	$\chi^2 = 6.684, p = 0.01^\dagger$
Patient issues	74.42% (64)	86.27% (44)	
Issues of informed consent	50% (43)	76.5% (39)	$\chi^2 = 9.336, p = 0.002^*$
Vulnerability	29.1% (25)	68% (34)	$\chi^2 = 19.509, p = 0.0001^*$
Subgroups discussion	54.7% (47)	39.2% (20)	
Therapeutic need	11.6% (10)	70.6% (36)	$\chi^2 = 49.901, p = 0.0001^*$
Philosophical issues	66.27% (57)	82.35% (42)	

* $p < 0.01$.† $p < 0.05$.

3) Publication bias:

Most of the negative randomized control trials concerned with psychotropic drugs do not get published. [Pharmaceutical data set]¹⁴

[T]heir apparent exclusion from the data pool, as well as from Medtronic's report, is of some concern (i.e. it may have contained cautionary or unfavorable remarks). [Neurosurgery data set]¹³

4) Where to draw the line between research, treatment, and innovation:

The most difficult task for physician-investigators is recognizing that their agendas may not be the same as or in the best interest of their subject-patients. [Pharmaceutical data set]²²

[...] the distinctions between research, innovation, and treatment become almost indistinguishable in procedures for serious conditions where no standard alternative therapy would provide a reasonable harm/benefit balance. [Neurosurgery data set]²¹

In addition to quantitative differences, there were also important content-relevant differences between the data sets. For example, pharmaceutical articles approached issues such as medical education and industry, which are seldom raised in the context of the neurosurgery data set: "Researchers who have their research or teaching activities funded by pharmaceutical companies may also experience [a] moral dilemma."⁵³ Another difference is related to issues of studies sponsored by industry. In the case of pharmaceuticals: "Studies sponsored by pharmaceutical companies are more likely to have outcomes favorable to

the sponsor. Industry sponsorship also results in restrictions on publication and data sharing, and in selective reporting."¹⁴ In the case of neurosurgical devices, investigators often rely on the medical device company donating or making available the equipment for the surgery: "Medtronic also often makes a practice of donating the equipment for the surgery used in highly experimental and investigational uses."¹³

Issues of intellectual property, startups, and the Bayh-Dole Act, while relevant for both types of interventions, were found only in the neurosurgery data set: "[The Bayh-Dole Act] is especially significant for DBS research, which revolves around access to costly proprietary devices."¹³ Marketing, including direct-to-consumer (DTC) advertising, was almost uniquely mentioned in the pharmaceutical data set: "Private companies have set campaigns to shape a favorable climate of opinion for their drugs."¹⁵

There were also differences regarding medical professional issues. In the pharmaceutical data set half of all articles (51.2%) raised medical professional issues, whereas only one-third of neurosurgery articles touched on the issue (31.4%). However, the pharmaceutical data set focused mostly on medical professional issues involving psychiatrists, who are more likely to prescribe these medications, whereas the neurosurgery set focused on issues involving neurosurgeons.

Discussion

Our results suggest that the potential ethical implications of industry-professional relationships, including

TABLE 3. Comparison of topics in the pharmacological and neurosurgical psychiatric interventions discussion regarding COIs

	Pharmaceuticals	Medical Devices
Financial ties & improper inducements	<ul style="list-style-type: none"> Financial ties with industry: researchers, clinicians, advisory committee members.^{7,15,26,29,42,50,51,53} Improper inducements, including free drug samples, free continuing education courses in resort locations, expensive dinners.^{7,25} Financial incentives for “successful recruitment and enrollment.”⁴⁴ “Receipt of gifts adversely affects physicians’ prescribing behavior.”⁴² 	<ul style="list-style-type: none"> Conflicting roles in industry-sponsored research (e.g., company advisor, consultant, honorarium, and/or shared patents).^{13,17,48} Improper inducements, including study contracts, professional advancement, consultant fees.^{13,17}
Medical education & industry	<ul style="list-style-type: none"> Research or teaching activities funded by pharmaceutical companies.^{15,26,53} Marketing biases in therapeutic information.^{42,51} 	<ul style="list-style-type: none"> “The dissemination of miracle stories presents an educational vulnerability.”²¹
Editorial practices & disclosure	<ul style="list-style-type: none"> Ghost writing, publications that are “infomercials.”^{7,14,25,34} Ineffectiveness of disclosure policies.⁴⁰ Undermines public trust, “not simply in a particular paper or journal, but in the integrity of the scientific enterprise as a whole.”⁷ Public trust in psychiatrists has been affected from failure to report conflicts of interests.⁵¹ 	<ul style="list-style-type: none"> “Investigators should be transparent with disclosures of financial conflicts of interests” in all informed consent discussions.³⁹ Questionable disclosure practices.¹³ “Undermine the research both by throwing doubt over the legitimacy of the study design and analysis as well as by risking a loss of public trust.”^{13,39}
Publication bias	<ul style="list-style-type: none"> Studies sponsored by pharmaceutical companies are more likely to have outcomes favorable to the sponsors.^{14,27,51} Restrictions on publication and data sharing.^{16,26,40} Methods for detecting and correcting for publication bias have limitations.¹⁶ 	<ul style="list-style-type: none"> Exclusion from the data pool and industry report.¹³ Industry personnel involved in targeting and analysis.¹³
Industry-funded trials	<ul style="list-style-type: none"> Evidence bias.^{14,16,34} “Pharmaceutical industry does not generally fund long-term studies of medications.”²⁴ 	<ul style="list-style-type: none"> Disincentive to formally study surgical procedures that are not device related.²¹ Lack of competitors in the DBS market. Industry donation of the equipment for the surgery used in highly experimental and investigational uses.¹³ “Market based approach to inquiry.”¹⁹
Bayh-Dole Act, intellectual property, & start-ups		<ul style="list-style-type: none"> The revision of the Bayh-Dole Act to suspend the transfer or sale of intellectual property rights until early stage research (Phase I trials) is completed.^{13,17} Intellectual property information related to the FDA’s approval is not available.¹³ “Granting a humanitarian device exemption [...] could be a consequence of inadequate enforcement of existing FDA rules or corporate economic motivations to broaden the applications of existing technologies.”¹⁷
Marketing, advertisement, media	<ul style="list-style-type: none"> The role of advertising.^{15,16,34,49} Drug company promotion and propaganda.⁶ “The growing role of advertising agencies in the business of conducting clinical trials of pharmaceuticals.”⁷ DTC advertising.^{26,51} 	<ul style="list-style-type: none"> The role of the media in communicating developments in this area.²¹
Research, innovation & treatment	<ul style="list-style-type: none"> Treating clinician versus research clinician.^{14,22,42,55} “Abuse of the trust implicit in the relationship between patient and doctor.”³⁴ “Doctors themselves seldom have much direct knowledge about the research used to justify the use of psychiatric drugs.”⁶ 	<ul style="list-style-type: none"> “The distinctions between research, innovation, and treatment become almost indistinguishable” in these types of procedures.²¹ Ambition and desire for fame.¹⁸ Investigational new device.¹⁷
Recommendations & guidelines	<ul style="list-style-type: none"> “While the FDA requires IRB approval of study advertisements, there is no such requirement in the Common Rule.”⁴⁴ “The new standards do not have the force of law.”⁷ 	<ul style="list-style-type: none"> Disclosure of COI to regulatory bodies and potential enrollees.^{13,18,39,48} “There are currently no guidelines regulating innovative surgery;” “there are limits to relying on self-enforcement practices of corporations.”¹³

COIs, have been largely neglected in the discussion of ethics issues raised by psychiatric neurosurgery. This is particularly true for neurosurgery involving implantable devices (such as DBS) or requiring special devices (such as radiosurgery). Our results also underscore the similarities and differences in the way in which different concerns manifest with regard to the 2 types of treatment. Here, we draw on both the existing bioethics literature and the findings of our comparative analysis to discuss these differences (Table 3).

Erickson-Davis¹³ addressed the lack of discussion of COIs in the bioethical analysis of DBS for obsessive-compulsive disorder (OCD), attributing it to a tendency among bioethicists to focus on clinical decision-making rather than on the broader context within which these decisions are made. Our results suggest that this is not the complete story, as there is a robust discussion of COIs and industry-related concerns in the literature on pharmacological interventions in psychiatry.^{1,2,7–10,14,25,28,30,34,39,58} Several factors provide at least a partial explanation for the relative lack of discussion of COIs in psychiatry and medical devices.

DBS Is New, Pharmaceuticals Are Not

First, DBS is both a relatively new and a relatively rare treatment in psychiatry. Psychiatric neurosurgery almost disappeared from the medical arsenal in the 1970s because of reactions to the use of lobotomy, while at the same time the first psychopharmacological agents started to be used.⁵⁶ This created a gap of several years in which the pharmaceutical industry dominated the psychiatric therapeutic arena. It was only after 1999 that psychiatric neurosurgery saw a revival.^{33,38,37} Moreover, unlike DBS, the early days of psychiatric neurosurgery did not involve the medical device industry, which has proprietary interests in both the equipment and the techniques now being used.⁴⁵

In contrast to DBS, there is a long history of the use of pharmaceuticals in psychiatry and of public discussion of scandals related to pharmaceuticals (e.g., the use of antidepressants in children). There is also broad awareness of pharmaceutical industry influence on medical practice and medical education.^{23,26,43,51,57} This includes the use of opinion leaders in specific areas of medicine to promote the company's products, as well as gifts ranging from mundane office supplies to luxurious weekends as medical "education" events.

The impact of the pharmaceutical industry in attracting the attention of both bioethicists and the public regarding COIs can also explain why in some of the neurosurgery articles, the COIs mentioned were more directed toward the pharmaceutical industry than the medical device industry. The last-resort nature of these procedures, their extensive workup, and the fact that they have not been proven effective might also be reasons for why COIs may not have been as broadly discussed as they are in the case of pharmaceuticals.

Restriction to Treatment-Resistant Disorders: Less Room for Overuse of Invasive Medical Devices

Second, the very specific use of psychiatric neurosur-

gery interventions (severe, treatment-refractory psychiatric disorders) and their experimental nature may mean there is less room for overuse of medical devices. This may, however, be an overly optimistic view, as 2 of the neurosurgery papers discussing COIs extensively were connected to the humanitarian device exemption granted to Medtronic for one of its neurostimulators for treatment-refractory OCD. Both Fins et al.¹⁷ and Erickson-Davis¹³ suggested that DBS will be increasingly used as companies attempt to increase their market share. This increase may come not only by characterizing more patients as good candidates for DBS, but also for expanding the range of conditions for which DBS is used (Fig. 1).

The most recent World Society for Stereotactic and Functional Neurosurgery meeting, whose theme was "Emerging techniques and indications," held a premeeting workshop precisely on surgery for psychiatric disorders. The workshop made obvious the tensions between those who seem very optimistic about the possibilities and others stress the challenges ahead, including the complexities of targeting, as well as the fact that psychiatrists in general are unlikely to make referrals for this type of more invasive intervention. The workshop also highlighted the trend toward exploring new indications, as well as new techniques, in psychiatric neurosurgery. Similarly, in our data set, many papers discussed issues of innovation and/or new indications for which DBS might be developed. While one-third of these papers also discussed COIs, explicit links between these issues were not made.

As new psychiatric indications are explored with the goal of reaching US FDA approval or expanding the market for current devices (e.g., not necessarily for patients whose condition is treatment refractory), the issue of COIs becomes more salient.

Moreover, while relatively few neurosurgeons and psychiatrists have been involved in these procedures, some of them are already involved in patents for brain regions⁴⁵ and companies connected to neuromodulation. In this regard, disclosure to both research participants and patients becomes a key issue. A systematic review looking at the

FIG. 1. Clinical trials for psychiatric neurosurgery. Data from clinicaltrials.gov, last updated August 2017. PTSD = post-traumatic stress disorder.

impact of disclosing financial ties in research and clinical care found that in 6 of the 10 studies assessing the importance of disclosure, most patients and research participants believed financial ties should be disclosed, and that among the 7 studies assessing willingness to participate in research, approximately 25% of participants reported less willingness to participate after disclosure.³¹ The review was not specific to psychiatric treatments; thus, more research is needed in the specific case of psychiatric neurosurgery. In particular, patients who become candidates for a last-resort therapy might not properly consider the implications of potential COIs as a result of their desperation for a possible cure.

Differences in the Type of Treatment

A third reason for COIs being less frequently discussed with regard to neurosurgical interventions may be the differences in the nature of the treatments themselves. Patients may continue to take—and to pay for—a medication (or multiple medications) for years. Neurosurgical treatments, for example, require an initial higher cost and an invasive procedure, compared with pharmacological treatments. Yet patients do not continue to pay for the devices until batteries or hardware need to be replaced. This may change, however, if the quest for more market share leads some medical device companies to come up with schemes in which certain add-ons, software updates, or licensing fees and ongoing maintenance of the devices create extra charges on a more continuous basis.

While discussion of COIs and industry involvement in our neurosurgery data set focused primarily on DBS, there have already been cases of other medical devices entangled in COIs. A 2006 case involved an article reviewing the efficacy and safety of vagus nerve stimulation as a treatment for depression.³⁶ None of the prominent academic psychiatrists who authored the paper, including Charles Nemeroff, who was the editor of the journal in which the article was published and the principal author of the paper, disclosed their financial ties to Cyberonics, the company making the implanted device.

Differences in the Relationships Between Industry and Professionals

Another key difference is the professionals involved. In the case of pharmaceuticals psychiatrists are often involved, whereas in the case of neurodevices neurosurgeons are involved. Another difference is the influence of industry on clinical trial design and results. COIs are well recognized in research on pharmaceuticals. Industry-sponsored trials are more likely to show results that favor the sponsor's drug.^{4,30} Moreover, clinicians who participate as investigators in industry-sponsored studies face conflicts arising from their dual roles as clinician and as investigator. As investigators, they often have a financial incentive to enroll patients,^{44,47} because industry sponsors pay for the successful recruitment and enrollment of study participants. There is also evidence that these commercial sponsorships have an impact on the prescribing practices of physicians.

In the case of medical devices, there is also a close relationship between clinicians and industry, although the details of the relationship differ in important ways from the

pharmaceutical case. For one thing, neurosurgeons, instead of being contractors for a trial of a drug that “belongs” to an industry sponsor, might hold patents related to a neurosurgical device, have shares in, or be on the board of directors of a medical device company. In addition, in some cases researchers depend on industry lending them the equipment to conduct studies. As Fins and colleagues noted,

[o]nly industry can practically design, or readily provide existing devices for use in clinical trials. While university engineers might design early prototypes, collaboration with an existing device maker—or significant venture capitalization to engineer a start-up venture—is necessary to meet stringent FDA investigational device exemption (IDE) applications which requires the achievement of a high level of design, manufacture, and oversight.¹⁹

These constraints on researchers make it necessary to collaborate with industry to do research.

Another important difference, both in our data set^{13,17} and in the broader discussion of COIs,^{19,20} is the more extensive discussion of the Bayh-Dole Act and patents for medical devices compared with pharmaceuticals. This seems to be related to the stagnation in terms of developing successful pharmacological drugs, and instead focused on innovation and patents that come from developing new neurodevices.

There are also potentially important differences in the relationships clinicians have with representatives of pharmaceutical companies and those of device manufacturers. It is well recognized that pharmaceutical sales representatives may influence prescribing practices through their relationships with prescribers. It is also recognized that physicians themselves may not fully appreciate the extent of this influence, although empirical studies show that such an influence does occur.²⁶ However, these sales representatives are not present when physicians are interacting with their patients. By contrast, in the medical device industry, clinicians are not only “educated” about the latest advances in the industry but are constantly exposed to the representatives, who are present in each of the surgeries and play a key role in helping with programming and setting the device. While it is not clear from our exposure to the literature that this will be the case in terms of investigational use, it seems plausible considering that industry would not provide existing devices for clinical trials otherwise.

Yet, even when the interactions with industry are closer in the medical device industry arena, the interactions with the pharmaceutical industry are more wide reaching. This explains, in part, why a great deal of the discussion regarding COIs involves the pharmaceutical industry and not so much the medical device industry.

Another difference in terms of industry and marketing practices is the heavy, and oftentimes DTC, advertising pharmaceutical companies engage in.^{7,11,16,34,51} Until recently, medical devices have not engaged so actively in the practice of DTC advertising to patients, but that is changing as medical devices aim to increase their market share. Although outside the scope of our data set, a clear example of this is the appearance of transcranial magnetic stimulation, a medical device recently approved by the FDA for depression, on *The Dr. Oz Show*.¹²

Conflicts of Interest: (Near) Monopoly Held by Device Manufacturers

The extent of competition between different companies is another big difference between pharmaceuticals and neurodevices. In the case of pharmaceuticals, there are various companies that market similar products, including, for older medications, generic drugs. However, in the case of neurostimulators, Medtronic is the world's largest and most prominent manufacturer of DBS devices, and until recently it was the only company with a commercially available DBS system. Although Medtronic continues to dominate both commercially and in terms of research worldwide, St. Jude and Boston Scientific have had ongoing research and are approved in Europe for Parkinson disease, essential tremor, and OCD, and are currently active in clinical trials for psychiatric DBS. Given the still-limited competition in the psychiatric neurosurgery market, the tight connections between these companies and the research being conducted deserves further scrutiny.¹³

Considering all these points, we see COIs as a neglected issue in the discussion of ethics concerns regarding medical devices in psychiatry. As developments continue, more research will be needed to establish whether or not the topic is better addressed, to draw on lessons learned from the discussion regarding the pharmaceutical industry, and to develop better approaches to address those areas that are unique to the medical device industry in terms of COIs.

Conclusions

There are several areas, both regarding pharmaceutical interventions and medical devices, where COIs and relationships with industry overlap. That is why some recommendations can apply to research results sponsored or supported by pharmaceutical, medical device, or biotechnology companies.³ However, there are also substantial differences, such as the type of relationships found between pharmaceutical and medical device representatives. Overall, COIs involving medical devices have been inadequately analyzed, and standards for assessing and managing these COIs still need to be developed. Proper management is key to ensure transparency in research design and publication of results, to maintain trust both between the public and researchers and between clinicians and patients, and to sustain an evidence-based approach to inquiry and treatment that ensures the protection of research participants. The fact that little has been written about COIs in the psychiatric medical device industry does not make the issues less problematic than those related to pharmaceuticals.

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Disclosures

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Author Contributions

Conception and design: Cabrera. Acquisition of data: Cabrera, McKenzie. Analysis and interpretation of data: Cabrera, McKenzie, Bluhm. Drafting the article: Bluhm. Critically revising the article: all authors. Reviewed submitted version of manuscript: Cabrera, Boyce, Bluhm. Approved the final version of the manuscript on behalf of all authors: Cabrera. Statistical analysis: Cabrera. Administrative/technical/material support: Cabrera. Study supervision: Bluhm.

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