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RESEARCH ARTICLE

A Quantitative Analysis of Undisclosed Conflicts of Interest in Pharmacology Textbooks

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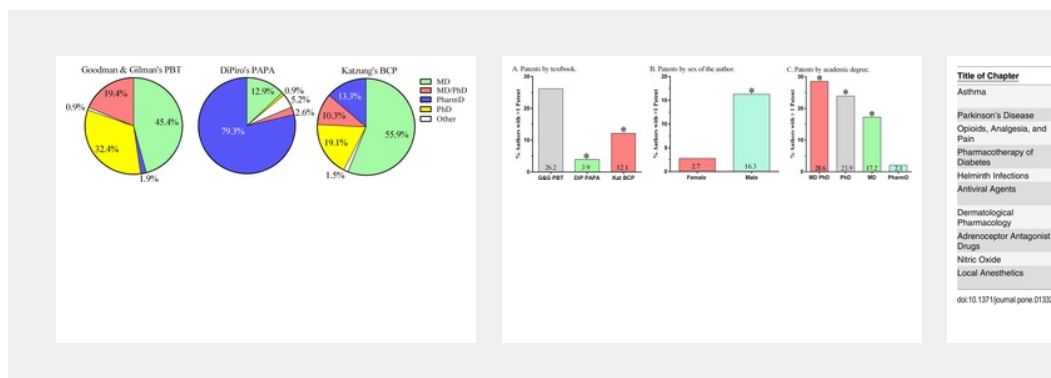
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Abstract

Background

Disclosure of potential conflicts of interest (Col) is a standard practice for academic journals but not for educational materials. The goal of this investigation was to determine whether the authors of pharmacology textbooks have undisclosed conflicts of interest and to identify author characteristics associated with Col.

Methods and Findings

The presence of potential Col was evaluated by submitting author information (name, gender, and affiliation) to a patent database (Google Scholar) as well as a database of author compensation (\$USD) received from 15 pharmaceutical companies (see Table 1 for Docs). All publications (N = 410) of the ten highest compensated authors in 2013 and indexed in Pubmed were also examined for disclosure of potential Col. Of the authors, 134 patents had been awarded (Maximum = 18/author) to ten authors. Relative to *DiPiro's Pharmacotherapy. A Pathophysiologic Approach*, *Goodman and Gilman's Pharmacological Basis of Therapeutics* and *Katzung's Clinical Pharmacology* were more frequently patent holders (OR = 6.0). Female authors were less likely than males to have > 1 patent (OR = 0.15, P = 0.002). The total compensation received by 53 authors (Range = \$299 to \$310,000/author). Highly compensated authors were from multiple fields including oncology, psychiatry, neurology, and cardiology. The maximum number of additional companies, not currently indexed in the patent database, for which an author had potential Col was 73.

Conclusions

Financial Col are common among the authors of pharmacology and therapeutics textbooks. Full transparency of potential Col, particularly patents, should be a standard procedure for future editions of educational materials in pharmacology.

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Introduction

Conflicts of Interest (ColS) may occur when an individual's professional conflict with their personal interests or when their professional responsibilities (e.g., clinician versus researcher). The credibility and public trust in science depends on how fully and transparently ColS are handled. Many, but not all, biomedical journals have developed detailed policies over the past decades to require authors to disclose financial ColS [1–3]. Authors with a ColS are more likely to report findings that are consistent with the interests of the research sponsor, such as treating cardiovascular diseases [4], cancer [5–6], and psychiatric disorders [7].

Recently, the author of a widely employed psychopharmacology textbook identified several pharmaceutical companies that he has consulted for, served on the speaker's bureaus, and received support for travel or research. This prompted the examination of other psychopharmacology textbooks which revealed that ColS are typically unreported. Females who were the first or senior author of empirical reports in psychopharmacology were more likely to declare the source of their funding and less likely to report a ColS with the pharmaceutical industry [14]. Therefore, the objectives of this report were to: 1) determine the prevalence of ColS among authors of widely used educational and reference materials in psychopharmacology and 2) to identify whether there are differences in the qualitative characteristics of ColS based on the textbook or author characteristics.

Materials and Methods

Ethics Statement

This investigation involved evaluating potential ColS by submitting a list of authors to multiple databases. As such, the chairperson of the Husson IRB indicated that this study did not constitute human research. Although all information reported in this report is publicly available, the names of individual authors are not listed in the figures to protect sensitive information may be obtained by contacting the authors.

Procedures

The most recent editions of four commonly used books were selected for analysis.

Gilman's Pharmacological Basis of Therapeutics [10] (PBT, 12th edition) is a comprehensive pharmacology reference with a distinguished history. PBT was first published in 1970 and has historically been considered the "blue bible of pharmacology" [11]. Both basic and clinical pharmacology are represented but PBT includes a strong emphasis on clinical pharmacology and neuropharmacology. PBT is widely used in diverse areas of medical education and training of pharmacists and research pharmacologists. *Katzung's Basic and Clinical Pharmacology* [13] (BCP, 12th edition, 2012) is a highly readable text used widely in the medical and allied health fields. The longest section in BCP is on antineoplastic (chemotherapeutic) drugs. *DiPiro's Pathophysiology: A Pathophysiologic Approach* [14] (PAPA, 9th edition, 2014) is a cornerstone of the pharmacy curriculum. The longest section in PAPA is on infectious diseases. As psychiatry has received increased attention for CME [16–18], the author of a collection of resources in *Essential Psychopharmacology* [9] (SEP, 4th edition, 2013) was also able to identify names from PBT, BCP, PAPA, and SEP, with the exception of those related to introductory material/general principles (Section I in PBT and BCP), which were found in three databases.

1. Google Scholar.

Each author's name (N = 403) and "patent" was input into the Google Scholar (<http://scholar.google.com/>) search engine. The checkbox "include patents" was selected to identify patents where the author was listed as an inventor or co-inventor from 1995 until present (2014). This broad window was selected because patents granted from mid-1995 provide protection for up to seventeen years, covering the period during which the chapters were originally authored. For this analysis, "patent" is inclusive of both applications and an issued patent as both are listed as potential Col [1]. Names of individuals with at least one patent were identified in the database (<http://www.freepatentsonline.com/>). The primary dependent variable was the presence or absence of patents although the quantity of patents was also recorded.

2. ProPublica's Dollars for Docs (PDD).

The database by ProPublica (<http://projects.propublica.org/docdollars/>) provides information on the compensation received from from fifteen pharmaceutical companies began contributing data in 2009 (Cephalon, Eli Lilly, GlaxoSmithKline, and Pfizer) or 2010 (Allergan, AstraZeneca, Johnson and Johnson, Merck, and Novartis). The service provided by each author from 2009 to 2012 is categorized as speaking, consulting, meals, travel, other, or a combination. One search criterion was the state of the author's employer and another nationwide in order to identify remuneration that was associated with a practice site in another state. The search was provided (e.g., \$90,000–100,000) than the mid-point (e.g., \$95,000). The default setting is to only include values \geq \$250. Only health care professionals (MDs, PharmDs) with a United States affiliation were eligible to have a PDD entry. Dependent measures included the presence or absence of a PDD entry and the compensation received.

3. Pubmed.

Additional search of the ten highest compensated authors was conducted in Pubmed.

(<http://www.ncbi.nlm.nih.gov/pubmed>). Col information was extracted = 410, Min = 7, Max = 114/author) published in the past five years (2 any additional companies (biotechnology, medical device, or pharn currently covered by PDD. No adjustments in the total number of co for companies that have subsequently merged, split, or are no long

Data-Analysis

Statistical analysis was conducted using Systat (San Jose, CA), vers [Dataset](#)). An alpha < .05 was considered significant but statistics th conservative thresholds (e.g., .0005) were also noted. Analyses ex: characteristics (the textbook contributed to, whether an author con edition of the same textbook, highest professional degree, country, sex) were associated with Cols. In ambiguous instances (e.g., only t provided), author sex was determined by consulting the National Pl Enumeration System or a general internet search. Total compensat most to least and the top ten authors were examined separately. As editors have the potential to exert substantial influence on textboo compensated author/editor was also determined. Non-parametric : conducted with a chi-square (e.g., presence of a PDD entry) or the C Figures were prepared with Graphpad Prism (La Jolla, CA), version 6 expressed as the SEM. Potential inconsistencies between Cols ider Pubmed were defined as instances where a company or activity wa manuscript but not in PDD for a company that supplied data to PDD.

Results

Author Characteristics

There were some similarities as well as differences among the three pharmacology books (note that SEP is a single-author textbook and following sections). A greater proportion of the PAPA authors were f either BCP (19.7%, $\chi^2(1) = 22.42, P < .0001$) or PBT (11.2%, $\chi^2(1) = 5$ majority of BCP authors had an MD degree whereas over three-qua PharmD degree ([Fig 1](#)). The preponderance of authors contributed = 92.6%, PBT = 87.9%, BCP = 83.3%). Slightly less than half of PBT aut contributed to the previous edition of this book which was significant (87.9%, $\chi^2(1) = 31.84, P < .0001$) or the PAPA (80.9%, $\chi^2(1) = 44.62$, Less than one-tenth of authors had affiliations outside of the U.S. (P PAPA = 4.8%).



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Fig 1. Highest academic degree of the authors by textbook.

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Patents

The authors had been granted 134 patents (Maximum/author = 18) titles that showed a particular overlap with the content of a chapter. The percentage of authors having at least one patent (11.4%) differed significantly between textbooks. BCP was larger than PAPA ($\chi^2(1) = 6.38, P < .025$). PBT was also greater than PAPA ($\chi^2(1) = 37.01, P < .0001$) and BCP ($\chi^2(1) = 4.89, P < .05$, Fig 2A). A complete list of patent titles for each textbook may be obtained from B.J.P. Females were less likely to have at least one patent (OR = 0.15, $P < .0005$, Fig 2B). Highest academic degree was associated with having ≥ 1 patent with PharmDs being significantly more likely than other degree holders (Fig 2C).



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Fig 2. Patents by author characteristics (* $P < .05$).

Goodman and Gilman's Pharmacological Basis of Therapeutics (PBT), Katzung's Basic and Clinical Pharmacology (Kat BCP), and Pharmacotherapy: A Pathophysiological Approach: (DiP PAPA), Katzung's Basic and Clinical Pharmacology (Kat BCP).

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Table 1. Example chapter and patent titles among authors of DiP PAPA, Katzung's Basic and Clinical Pharmacology, Goodman & Gilman's Pharmacological Basis of Therapeutics, or Katzung's Basic and Clinical Pharmacology.

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Compensation

PBT (30.4%) were more likely than PAPA authors to have a PDD entry. Similarly, BCP (26.0%) authors also had more entries than PAPA (OR PDD entry was less common among female (4.7%) than male (22.6%) authors. PharmDs (4.9%) were less likely than either MDs (32.1%, $\chi^2(1) = 19.40, P < .0001$) or MD/PhD (29.0%, $\chi^2(1) = 19.40, P < .0001$) authors to have a PDD

A total of \$2,411,080 was received by 53 authors (6 females and 47 to \$310K/author). The largest category of support was for speaking compensation/author) followed by consulting (27.0%), research (23 combination (6.2%), and other (2.4%).

Over half (62.1%) of the total remuneration was to the top ten highest authors. These authors and the activities they received compensation 3A. The most compensated authors represented a variety of specialties: oncology, psychiatry, neurology, urology, and cardiology. Four authors received a majority (>80%) of their support for research although two others were primarily for consulting and another exclusively for speaking. Fig 3E providing compensation. Three authors received the majority of the support from Pfizer and three more from Pfizer. Four PBT and three BCP authors were in the top ten. The highest ranked author/editor was at position #29 with \$ compensation.



Examination of recent manuscripts revealed many additional compensation entries (Mean = 6.9; Median = 7.5, Min = 0, Max = 73) that provided compensation to authors. Inconsistencies between PDD and the publications indexed in PubMed were identified in 10/410 manuscripts or 2.4%.

Additional analyses were conducted among the subset of authors who received compensation. The average amount received was \$45,492 ± 8,846 (Median = 24,470). This amount was significantly different based on the textbook (PBT = \$56,888 ± 18,055; PAPA = \$31,038 ± 9,783) or author gender (Males = \$41,228 ± 18,894; Females = \$78,894 ± 49,380). However, MDs (\$47,724 ± 11,477) received more

(\$18,162 ± 7,786, $t(37.6) = 2.13, P < .05$). Dual-degree (MD/PhD) holders did not receive significantly more than others.

Discussion

The primary goal of this investigation was to determine if pharmacologists received appreciable financial disclosures (Col) or what could be reasonably perceived as financial disclosures. A detailed examination of three complementary resources, patents, financial disclosures, and a review of published manuscripts, the answer is clearly in the affirmative. PAPA currently do not consistently report financial Col. In contrast, PAPA notes the many companies that have provided remuneration. These authors consistently neglect to disclose patents. Overall, the financial Col were higher for the subset of textbook authors that had either a patent or a PDC. For example, two authors of a chapter in the inflammation section of PBT [10] together held 12 patents, many of which were highly relevant to the subject matter. The maximum compensation/author from pharmaceutical companies was \$18,162 which was distributed over two years. Notably, the compensation received does appear to be lower than that reported for a prominent "ethical" psychiatrist. Further, the frequency of ties with pharmaceutical companies in pharmacology textbooks appears less widespread than in other textbooks. Working group members responsible for recent editions of the Diagnostic and Statistical Manual of Mental Disorders [16]. Although this may be a reason for some of the other resources like the Diagnostic and Statistical Manual are now based on the large evidence base that the funding source has an appreciable interest in biomedical information is presented and how favorably it is portrayed. The systematic omission of financial Col in three of the four textbooks examined is an unacceptable practice.

The second objective of this report was to determine the factors associated with financial Col. Both patents and the compensation frequency were more common in BCP & BCP) relative to pharmacotherapy (PAPA) textbooks. Pharmacists, pharmacologists, physicians or PhD trained pharmacologists to have financial Col. Similarly, PharmDs were less likely than other professional degree holders to receive compensation from pharmaceutical companies according to a prior analysis from the PDD [21]. Possibly, individuals who become inventors or conducting pharmacology research may choose to receive training in medicine or as scientists rather than other allied health fields. The preponderance of authors were affiliated with institutions of higher education. These schools may have greater intellectual property infrastructure than other institutions to support the patent application process. Although not the primary objective of the study, the finding that males outnumbered females 4:1 in BCP and 8:1 in PAPA is just noteworthy, but also concerning. This is likely reflective of the gender disparity in publishing in academic medicine [22]. There were also pronounced gender differences in the likelihood of being a patent holder. Females accounted for only three of the highest compensated authors (#26, #6, and #1).

There are some reasons to believe that the total remuneration reported in this study is an under-estimate of the compensation provided by companies to authors.

companies began reporting to PDD in the same year or report all ca [21,23]. As many as 73 additional companies/author were identified in the acknowledgments section, the Col section, or the International Committee of Medical Journal Editors (ICMJE) Col form [1] and these are not currently included with detailed monetary values and supported activities in PDD. We are optimistic that future projects of this type will benefit from laws like the Payments Sunshine Act which will mandate more widespread disclosure with a low threshold [24,25]. Importantly, even quantifying the number of conflicts associated with is impeded by innocuous sounding foundation names in the acknowledgments section (e.g., the Foundation for Lung Cancer Prevention, and Treatment) which are largely fronts for commercial interests. If self-reported disclosure will continue to be an integral element of a Col policy, the authors who received a modest honorarium for contributing to a chapter but failed to list this on the ICMJE form [1] did not go unnoticed. This is reflective of either selective recall or more wide-spread under-reporting. The majority of authors were eligible to have a PDD entry, PDD does not currently include authors located outside of the U.S. or PhD scientists. Unfortunately, even the PDD currently overlooks non-physician investigators [25]. It is also noteworthy that four of the top ten highest compensated authors provided by the pharmaceutical companies that are indexed by PDD but were not identified with a PDD entry. One of these discrepancies is currently unclear but we can only hope that the PDD requires authors using a longer window of disclosure than the PDD currently

In the event the editors of these and other medical educational resources provided a detailed account of all relevant potential financial and non-financial conflicts, one then may speculate what impact this will have. Although there is an extensive body of empirical evidence [27,28], we currently believe that this is a good general practice which may have more of an influence on the director selecting materials for their classes than on the beginning medical student. Furthermore, requiring authors to provide COI statements and disclose COI issues with undergraduate students and encourage them to make disclosures later in their professional career and to look for COIs while prescribing advice. Similarly, greater transparency in disclosing potential conflicts may lead some editors to make different choices when selecting authors to contribute to

Three limitations and future directions of this report should be clear. First, although the resources selected for this study are highly influential, they are from a single country. Further study with other pharmacotherapy textbooks and pharmacology books with authors outside of the United States [29] would be particularly if, or when, resources like PDD become more widespread. Second, the presence and number of patents for each author was not reported. Many, perhaps the majority, are highly related to the chapter content. It would be to formally quantify the degree of overlap and this will require further study. While this study identified many potential Cols, we can not infer from these outside interests, either among individual authors or collectively, that they influenced the presentation of material in any way. Follow-up studies would be needed to determine the contribution that financial or non-financial Cols have on textbook content.

In conclusion, an appreciable portion of the content in pharmacology

the influence of undisclosed potential financial conflicts of interest frequently consulted by many practicing physicians as well as other professionals and are also integral to their education. If all authors textbooks in pharmacology, as well as other biomedical fields, could [1] for CoI disclosures and this information were made publically available in a database, this would be an appropriate first step to begin to remedy oversight.

Supporting Information

S1 Dataset.

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(XLSX)

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Author Contributions

Conceived and designed the experiments: BJP. Performed the experiments: BJP. Analyzed the data: BJP. Wrote the paper: BJP DAL HMT.

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