abstract

BACKGROUND AND OBJECTIVES: There has been an increasing focus on the relationship between pediatric prescribers and the biomedical industry. There is a lack of research, however, on the biomedical industry’s relationship with the professional medical associations (PMAs) of pediatric prescribers. We developed a systematic method to assess this relationship by evaluating PMA transparency and compliance with a set of 2009 best practice guidelines (BPGs).

METHODS: Nine PMAs rated as having the greatest influence on pediatric prescribers were examined. Two researchers independently coded publicly accessible information from the PMAs’ Web sites for transparency and compliance with 36 BPG recommendations. Using the coded data, an industry relationship index (IRI) score was developed to systematize comparisons across PMAs.

RESULTS: The PMAs demonstrated transparency and compliance with less than one-half of the 2009 BPGs (mean ± SD: 30.2 ± 15.6; range: 8–51 on the 66-point IRI scale). Two PMAs clustered in the high IRI (more transparent and compliant) group, 3 in the medium group, and 4 in the low group. There was no significant association of IRI group status and the PMAs’ number of members or age. PMAs were least compliant with recommendations that prohibit or limit financial relationships with industry.

CONCLUSIONS: PMAs with influence on pediatric prescribers have achieved only limited transparency and compliance with a set of 2009 BPGs, particularly with respect to financial separation from industry. Use of quantifiable standards of conduct facilitates comparisons between organizations and may enhance public trust in PMAs, preserving their ability to achieve organizational goals.

WHAT’S KNOWN ABOUT THIS SUBJECT: There has been increasing legislative and regulatory focus on the relationships of pediatric prescribers and industry. Pediatric professional medical association (PMA) and industry relationships, however, are relatively unstudied and lack a systematic method of assessment.

WHAT THIS STUDY ADDS: This cross-sectional study used a new quantitative scale, the industry relationship index, to systematically rate 9 pediatric PMAs with respect to best practice guidelines on interactions with the biomedical industry, revealing significant variation in PMA practices.
Professional medical associations (PMAs) both represent and influence medical practitioners. As such, PMAs offer a uniquely efficient portal for pharmaceutical and biomedical device companies (industry) to gain access to and influence medical practitioners, with pediatrics being no exception. Due to increasing legislative and public concerns regarding the pharmacologic treatment of the pediatric population, methods are needed to evaluate the relationship between industry and the PMAs of pediatric prescribers.

In 2007, Congress held hearings on the relationship between physicians and the pharmaceutical industry, with a particular focus on pediatric prescribing. US Senator Charles Grassley (R-IA) presented several industry-related conflict of interest cases that highlighted an overall lack of transparency regarding these relationships between physicians and industry. The hearings focused on the possible influence of industry support on pharmacologic treatment of pediatric patients, highlighting the particular vulnerability of this population and the need to better understand the practices of their prescribing physicians and accompanying PMAs. The resulting Physician Payments Sunshine Act required public disclosure of all industry payments to physicians that exceed $10,000. Although the law promotes greater transparency for individual practitioners, it does not apply to those practitioners’ PMAs, which have been left to continued self-regulation.

Industry support of PMAs was estimated at more than $1.5 billion in 2006 for educational activities alone. Varying standards and policies regarding financial disclosure by PMAs, however, have made it difficult to evaluate the importance of industry support to PMAs, the specific means of support, and the prevalence of conflicts of interest. Industry–PMA relationships can take a multitude of forms, ranging from industry funding and presence at a PMA’s annual meeting, to industry-funded research grants, fellowships, continuing medical education, and journal publications, to the leaders of PMAs receiving financial support from industry for research, speaking, and other activities. A number of authors have examined these relationships through qualitative or editorial articles. A common concept in the literature is the importance of transparency in PMA–industry interactions and that simply disclosing potential conflicts of interest is sufficient to minimize risks. Some authors maintain that financial contributions from industry threaten the mission and central purpose of PMAs and suggest that they be avoided entirely. Others have promulgated a concept of balance, suggesting that severing all industry ties would be unrealistic and endanger organizational goals. Overall, the literature reveals a lack of consensus on how to manage the risks and benefits of PMA–industry relationships and the absence of a comparative quantitative tool that could inform these debates.

In 2009, a group of physician leaders published a detailed set of best practice guidelines (BPGs) for PMAs in the Journal of the American Medical Association; these guidelines were designed to lessen or eliminate the risks of both actual and perceived industry influence on PMAs. The group recommended that PMAs work toward a ban on all industry support that was not readily recognizable as advertising and posited that greater transparency and compliance with the BPGs would help the PMAs achieve this goal. Subsequent authors have upheld these recommendations as achievable, practical steps for PMAs to take in regulating their relationship with industry. Since publication of the BPGs, PMAs have increasingly offered statements of general principles regarding their relationship with industry. Although this action reflects some initiative, it may also obscure the specific financial, educational, and professional relationships that the PMAs have with industry.

Despite the increased public focus on this area, there has been no published research, to our knowledge, that systematically evaluated and quantified the relationship between PMAs and industry. To that end, we developed a rating scale, the industry relationship index (IRI), to systematically assess PMA transparency and compliance with the 2009 BPGs. Our goal was to examine for potential relationships between the IRI score and PMA demographic characteristics, such as total annual budget, and assess for variation in BPG adherence.

METHODS

PMA Selection

Five physician leaders in the fields of pediatrics, child psychiatry, and developmental behavioral pediatrics were asked to identify PMAs with the greatest influence on pediatric prescribers. PMAs that were listed by ≥2 respondents were selected for study, resulting in 9 PMAs for study.

PMA Assessment

We operationalized the 2009 BPGs into 36 distinct recommendations (Table 1). In July 2013, each PMA’s Web site was independently assessed by 2 college-enrolled research assistants with no professional or personal ties to a PMA and who were blinded to each other’s results; Supplemental Appendix 1 presents the PMAs’ Web site URLs. Demographic characteristics of the PMAs were collected, including total annual budget, number of members, and PMA age and discipline represented (eg, physician, psychologist). The Web site information was coded “yes/no” for...
Compliance was defined as the PMAs’ stated adherence to, or publicly available evidence of adherence to, each recommendation.

Discrepancies between the 2 raters’ coding were resolved by an independent third rater (M.S.). There were 74 discrepancies of 324 (23%) ratings of transparency and 24 discrepancies of 324 (7%) ratings of compliance. Because a recommendation could not be rated transparency and compliance with each of the 36 recommendations. Transparency was defined as the ability to locate the relevant information on the publicly accessible portion of the PMA’s Web site.
for compliance if it was coded as nontransparent, the third rater reviewed all transparency discrepancies, ensuring that all data points were coded by at least 2 raters. If a discrepancy could not be resolved due to inaccessibility of the data, the PMA was coded as neither transparent nor compliant with the recommendation. This process yielded a final set of resolved ratings for analysis (Supplemental Appendix 2). Interrater reliability of the total IRI score for the 2 primary raters was $k = 0.58$ ($P < .001$), indicating a moderate level of agreement.\(^{13}\) Interrater reliability for compliance ($k = 0.49, P < .001$) and transparency ($k = 0.54, P < .001$) separately also had moderate levels of agreement.

**IRI Development and Analysis**

The IRI was developed to provide a quantitative method for rating each PMA’s transparency and compliance with the 36 recommendations. BPG recommendations 29 and 30 were excluded because they each pertained to PMAs with affiliated foundations, a condition met by only a few of the PMAs. Similarly, BPG recommendation 5 was also excluded because it was not feasible to assess based on publicly available information (Table 1). One point was awarded for evidence of transparency or compliance for each of the remaining 33 recommendations, yielding a maximum IRI score of 66 (higher score indicating more transparency and compliance). To facilitate interpretation of the results, visual binning was used to assess the distribution of the continuous IRI scores. The IRI scores clustered in 3 groupings and were categorized for analysis as low (IRI $0–21$), medium (IRI 22–46), and high (IRI 47–66).

Analysis of variance and $\chi^2$ analyses were then performed to investigate relationships between IRI groups and continuous and categorical PMA demographic variables, respectively.

**RESULTS**

There was a wide distribution in IRI scores among the 9 PMAs (range of 8–51 on the 66-point scale) (Table 2). The mean $\pm$ SD IRI score was 30.2 $\pm$ 15.6, indicating that the PMAs as a group were transparent and compliant with less than one-half of the BPG recommendations on average. PMA differences were highlighted by 3 tiers of IRI scores: high, IRI $\geq 47$ (American Academy of Neurology and American Academy of Child and Adolescent Psychiatry); medium, IRI 22–46 (American Academy of Pediatrics, American Medical Association, and American Psychological Association); and low, IRI $\leq 21$ (American Academy of Family Physicians, American Psychiatric Association, American Association of Nurse Practitioners, and Society for Developmental and Behavioral Pediatrics).

There were no significant differences between IRI groups (high, medium, and low) in relation to the PMAs’ number of members ($P = .22$), age ($P = .40$), or type of discipline represented ($P = .49$). There were, however, significant differences in the total annual budget according to IRI group, with the medium IRI group exhibiting a significantly higher average budget than both the low ($P = .045$) and high ($P = .044$) IRI groups.

Most PMAs were rated as transparent on recommendations for disclosure of financial relationships with industry (recommendations 6 [78%], 8 [67%], 32 [56%], and 35 [77%]). Few PMAs, however, were rated as compliant with recommendations for divestment or substantial limitation of financial support from industry (recommendations 1 [0%], 2 [11%], 7 [0%], 31 [33%], 32 [11%], and 34 [22%]).

**DISCUSSION**

Four years after publication of the 2009 BPGs, the majority of PMAs with the greatest influence on pediatric prescribers exhibited transparency and compliance with less than one-half of the BPG recommendations. Use of an IRI score allowed comparison of the PMAs and identified substantial variability in PMA conduct with respect to industry relationships.

### TABLE 2 PMA Demographic Characteristics and IRI Scores

<table>
<thead>
<tr>
<th>PMA</th>
<th>IRI Score (Range: 8–51)</th>
<th>Compliance Score (Range: 3–24)</th>
<th>Transparency Score (Range: 5–30)</th>
<th>Total Annual Budget (2011), $</th>
<th>No. of Members</th>
<th>Age (y)</th>
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<tr>
<td>American Academy of Neurology</td>
<td>51</td>
<td>24</td>
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<tr>
<td>American Academy of Child and Adolescent Psychiatry</td>
<td>49</td>
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</tr>
<tr>
<td>American Academy of Pediatrics</td>
<td>46</td>
<td>20</td>
<td>26</td>
<td>100 924 558</td>
<td>60 000</td>
<td>85</td>
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<tr>
<td>American Medical Association</td>
<td>34</td>
<td>14</td>
<td>20</td>
<td>217 700 000</td>
<td>225 000</td>
<td>186</td>
<td>Physician</td>
</tr>
<tr>
<td>American Psychological Association</td>
<td>23</td>
<td>8</td>
<td>14</td>
<td>119 025 649</td>
<td>134 000</td>
<td>121</td>
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<tr>
<td>American Academy of Family Physicians</td>
<td>21</td>
<td>8</td>
<td>13</td>
<td>75 898 603</td>
<td>110 600</td>
<td>86</td>
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</tr>
<tr>
<td>American Psychiatric Association</td>
<td>18</td>
<td>6</td>
<td>12</td>
<td>46 502 000</td>
<td>53 000</td>
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<tr>
<td>American Association of Nurse Practitioners</td>
<td>18</td>
<td>7</td>
<td>11</td>
<td>11 904 427(^{a})</td>
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<tr>
<td>Society for Developmental and Behavioral Pediatrics</td>
<td>8</td>
<td>3</td>
<td>5</td>
<td>509 304</td>
<td>700</td>
<td>31</td>
<td>Physician</td>
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\(^{a}\) Combined budget from the American Academy of Nurse Practitioners and the American College of Nurse Practitioners.

\(^{b}\) From the American Academy of Nurse Practitioners, which merged with the American College of Nurse Practitioners in January 2015.
Although it is largely unknown what factors might influence a PMA’s IRI score, the present study offers some possible areas of association. Larger annual PMA budgets were associated with only medium IRI scores, suggesting that a large annual budget may allow a PMA to meet some best practice standards but might also inhibit the PMA’s ability to have enough separation from industry to achieve a high IRI score. Interestingly, the 2 PMAs with the highest IRI scores had relatively small annual budgets, suggesting that a high level of compliance with the BPGs may require some resources but not so much that the PMA becomes substantially financially entwined with industry.

The IRI ratings also revealed a sharp divide in the type of recommendations that are followed. The most widespread transparency and compliance was with the 4 recommendations on disclosure of industry relationships, including financial arrangements. Conversely, few of the PMAs were compliant with the 2 recommendations that required divestment from financial relationships with industry or with 4 other recommendations that substantially limit other aspects of PMA–industry financial interactions. Thus, the studied PMAs were least compliant with recommendations that promote a financial separation from industry and most compliant with those that simply encourage disclosing potential conflicts of interest. Although some organizations may assume that disclosure of potential conflicts is an adequate shield from the risks financial ties with industry pose to public perception, it is a distinction that may be unappreciated by the public and legislators. For this reason (among others), the authors of the 2009 BPGs propose financial separation from industry as being in the best interest of PMAs and the medical profession as a whole.10

Although issues of conflict of interest are relevant for all PMAs, they may be of particular importance for the PMAs of pediatric prescribers. The dearth of clinical trials in pediatric populations, which has been well described, has led to high rates of off-label prescribing to children.14 To address this issue, the Pediatric Research Equity Act of 2003 sought to facilitate industry’s development of pediatric pharmacotherapy, including encouraging PMAs to identify unmet needs in the field and to work with industry.15 With IRI scores revealing that most PMAs comply with less than one-half of the BPGs, it is possible that an attempt to increase research in the field of pediatric pharmacotherapy has inadvertently affected the autonomy of the PMAs most active in serving the same population. As such, continued assessment of PMA–industry relationships is critical, and use of the IRI provides a systematic and quantitative means of comparison. Future examination of change in IRI scores over time may serve as a means of measuring the evolution of PMA–industry relationships.

We used publicly available Web site information and college-enrolled examiners to code for transparency and compliance. This approach raises several potential limitations, including a reliance on the Web searcher’s skill, the Web site’s content and ease of navigability, and college-educated information seekers. Web sites were used because they are now the primary repository for publicly available information about PMAs and many other organizations. To reduce the potential effects of the individual Web searcher’s skill, we used 2 independent raters and resolution of coding discrepancies by a third rater. Although a particular PMA may actually be in compliance with a recommendation and was coded otherwise due to lack of information on the Web site, the strength of the method is that it emphasizes the importance of transparency and reflects how real-world, college-educated users would likely encounter the information and form their perceptions. However, because publicly available information may not reflect the true status of a PMA, future research should attempt to validate the accuracy of the IRI by comparing ratings of publicly available information with each PMA’s internal policy and procedure documents (if they are made accessible).

Furthermore, because this study was the initial investigation examining the development and implementation of the IRI, we placed equal weight on each of the 36 recommendations. Future investigations could examine whether certain recommendations can be judged to be more important, and thus to have greater weight, than others. Future research could also perform qualitative surveys of PMAs to assess the relationship between transparency, compliance, and other PMA variables. Finally, this study focused on the PMAs judged to have the greatest influence on pediatric prescribers, which may limit generalizability. Future studies could rate a wider range of PMAs to further investigate potential factors related to IRI scores and examine how IRI scores change over time.

CONCLUSIONS

Despite an intensive legislative and public focus on the relationship between medical practitioners and industry, we found evidence of ongoing enmeshment of the PMAs of pediatric prescribers and industry, encompassing financial, educational, and professional activities. Using a set of 2009 BPGs, we developed a quantitative IRI, which revealed that the majority of the PMAs studied were in compliance with less than one-half of the recommendations, particularly those requiring a financial separation. Further application of the IRI may spur increasing standards for PMA–industry relationships and...
support a positive public perception of PMAs. For now, it seems that the PMAs of pediatric prescribers are still a long way from separating themselves from industry support and influence, increasing the risk that the public trust on which they trade may diminish.

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REFERENCES

ABBREVIATIONS
BPG: best practice guidelines
IRI: industry relationship index
PMA: professional medical association
# Pediatric Professional Medical Associations and Industry Guideline Compliance

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