Non-Research-Related Physician-Industry Relationships of Radiologists in the United States

H. Benjamin Harvey, MD, JD[a,b], Tarik K. Alkasab, MD, PhD[a,b], Pari V. Pandharipande, MD, MPH[a,b,c], Elkan F. Halpern, PhD[b,c], Anand M. Prabhakar, MD[a,b], Rahmi Oklu, MD, PhD[a,b], Daniel I. Rosenthal, MD[a,b], Joshua A. Hirsch, MD[a,b], G. Scott Gazelle, MD, PhD, MPH[a,b,c], James A. Brink, MD[a,b]

Abstract

Purpose: To evaluate non-research-related, physician-industry financial relationships in the United States, in 2013, as reported pursuant to the Physician Payments Sunshine Act (a provision of the Affordable Care Act).

Methods: In September 2014, CMS released the first five months (August 2013 to December 2013) of data disclosing physician-industry financial relationships. The frequency and value of non-research-related transfers in radiology were calculated and compared with those for 19 other specialties. Subanalyses of the frequency and value of such transfers in radiology were performed, based on state of licensure, radiologic subspecialty, nature of payment, manufacturer identity, and drug or device involved.

Results: A total of 7.4% (2,654 of 35,768) of radiologists from the United States had reportable non-research-related financial relationship(s) with industry during the 5-month period, the second-lowest level among the medical specialties evaluated. The average value of non-research-related transfers of value to radiologists, excluding royalties and licenses, was low ($438.71; SD: $2,912.15; median: $43.85), with <4% of radiologists receiving >$10 per month. Of all categories, that of food and beverage had the most transfers of value (86.0%; 5,655 of 6,577); royalties and licensure were associated with the greatest average value ($27,072.34; SD: $67,524.92). Although high-value relationships were rare, 57.8% (26 of 45) of radiologists who received a value >$1,000 per month held leadership positions in imaging enterprises.

Conclusions: Less than 4% of radiologists have non-research-related financial relationships with industry that are valued at >$10 per month, suggesting that meaningful, deleterious effects of such relationships on radiology practice, if present, are infrequent.

Key Words: Conflict of interest, industry interaction, financial relationship, Sunshine Act, ethics, regulation

J Am Coll Radiol 2015;12:1142-1150.

INTRODUCTION

Physician-industry relationships are pervasive in the US health care system. A 2003-2004 national survey of six specialties found that 94% of responding physicians reported having an industry relationship [1]. Similarly, another study found that 36% of institutional review board (IRB) members had ≥1 relationship with industry and sometimes participated in IRB decisions that had potential to affect companies within that field [2]. These relationships can take various forms, but often they are associated with transfers of value from industry to health care providers [3]. Examples include: industry-sponsored gifts; drug samples; complimentary food and beverages; subsidized continuing medical education (CME) activities; and payments for consulting, lecturing, or conducting clinical trials [3].

Although certain physician-industry relationships add value and improve patient care, conflicts arising from these relationships are potentially deleterious [4]. For instance, industry interactions can result in nonrational prescribing and purchasing behaviors, including increased utilization of the sponsoring company's product rather

[a]Department of Radiology, Massachusetts General Hospital, Boston, Massachusetts.

[b]Harvard Medical School, Boston, Massachusetts.

[c]Institute for Technology Assessment, Massachusetts General Hospital, Boston, Massachusetts.

Corresponding author and reprints: H. Benjamin Harvey, MD, JD, Department of Radiology, Massachusetts General Hospital, 175 Cambridge St, Suite 200, Boston, MA 02114; e-mail: hbharvey@partners.org.

Outside the submitted work, Dr. Hirsch reports personal fees from Medtronic, personal fees from Carefusion, and other fees from Intratech; and Dr. Gazelle reports personal fees from GE Healthcare.

1546-1440/15/$36.00 ■ http://dx.doi.org/10.1016/j.jacr.2015.04.017

than generic alternatives, despite higher costs and no demonstrable advantage [5-9]. As a result, physician-industry conflicts of interest have been implicated as preventable drivers of rising health care costs.

Responding to growing criticism, the Institute of Medicine called for full disclosure of physician-industry relationships, and health care systems around the country implemented staff policies restricting physician-industry interactions [10,11]. Similarly, the Pharmaceutical Research and Manufacturers of America trade group established a code of ethics to limit controversial marketing practices [12]. In addition, several states took legislative steps, most notably Vermont, which made it illegal in 2009 for drug and device manufacturers to offer or give any gift or food to health care professionals [13]. Pharmaceutical marketing expenditures decreased substantially in Vermont after the law was passed, but the law's impact on health care expenditures in the state is less clear [14].

As a part of the Patient Protection and Affordable Care Act (PPACA), the US Congress made an attempt to address physician-industry relationships. The Physician Payments Sunshine Act requires manufacturers of drugs, devices, and medical supplies covered by federal health care programs to track and report certain payments or transfers of value $\geq$\$10 to health care providers, as well as certain ownership interests [15]. Annually, at the end of the reporting period, CMS makes the data available to the public via the Internet.

Recently, the first year of reporting data were made publicly available, offering one of the most complete assessments to date of physician-industry financial relationships in the United States. Data were reported for three main payment types: general payments ("non-research related transfers"), including transfers of value not connected with a research agreement or protocol; research payments, including transfers of value connected with a research agreement or protocol; and physician ownership information, including ownership or investment interests in applicable manufacturers. The purpose of this study is to evaluate non-research-related financial relationships between radiologists and manufacturers of drugs, devices, and medical supplies in the United States in 2013 that were reported pursuant to the Physician Payments Sunshine Act.

METHODS

CMS publicly released a comprehensive dataset of disclosures regarding financial relationships that were not made in connection with a research agreement or research protocol, and were between manufacturers of drugs, devices, and medical supplies, and US health care providers [16]. The dataset was composed of individual records of each transfer of value, including physician name, physician specialty, state of licensure, value of transfer, nature of payment, manufacturer identity, and device or drug implicated (if applicable). Reported financial relationships included payments or transfers of value $\geq$\$10 provided to physicians, including but not limited to, royalty or license payments, food and beverages, gifts, education, consulting fees, travel and lodging, honoraria, and non-CME-accredited speaker fees. The relationships were tracked and reported to CMS by applicable manufacturers, as mandated by law.

The dataset represents records accumulated during a five-month period, from August 1, 2013 to December 31, 2013. Relationships that may have occurred during this period, but did not have potential to be discovered because the related information was not released in the initial dataset, include: data submitted late, data not associated with a physician or teaching hospital, disputed records that were not corrected by the end of the review and dispute period, and records flagged by a manufacturer for delay in publication.

The frequency and value of transfers to diagnostic radiologists were compared with those for physicians from 19 other specialties. Within the radiology specialty, patterns of transfers were sought based on state of licensure, radiologic subspecialty, nature of payment, manufacturer identity, and drug or device involved. If the transfer of value was related to a covered drug or biologic, then the manufacturer had to report marketed names; if the transfer of value was related to a covered device or medical supply, then the manufacturer had to report the marketed name, product category, or therapeutic area. This product-specific reporting was required for any category of general payment (entertainment, food, travel, consulting, etc.), as long as the manufacturer deemed the payment to have been made to further a covered product, such as marketing or educational efforts for a vascular device.

Given notable differences between payments made for royalties or licenses (royalty-based payments) and the other forms of non-research-related payments (non-royalty-based payments), these two groups were analyzed separately. For instance, royalty-based payments constitute a minority of the financial relationships ($<$1%) but are associated with a markedly higher value of transfers; they therefore skew value calculations if they are not isolated. For all radiologists with total non-royalty-based payments of $\geq$\$5,000, a focused online search was performed to determine if the radiologist held a leadership position in an academic or private imaging enterprise (such as the titles of director, division chief, vice chairman, or chairman) during the study period.