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Virtual Mentor

American Medical Association Journal of Ethics
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THE CODE SAYS

The AMA *Code of Medical Ethics*' Opinions on Physicians' Relationships with Drug Companies and Duty to Assist in Containing Drug Costs

Opinion 8.061 - Gifts to Physicians from Industry

Many gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

(1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.

(2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).

(3) The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

(4) Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

(5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional, or specialty medical associations.

(7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

Issued June 1992 based on the report "Gifts to Physicians from Industry," adopted December 1990; updated June 1996 and June 1998.

Opinion 8.135 - Cost Containment Involving Prescription Drugs in Health Care Plans

When health care plans, whether publicly or privately financed, establish drug formulary systems, physicians are obligated to advocate for formularies that meet the medical needs of their patients.

(1) Physicians should maintain awareness of plan decisions about drug selection by staying informed, where appropriate, about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influences on formulary development should notify the proper regulatory authorities.

(2) When scientifically based evidence is available, physicians are ethically required to advocate for changes to the formulary that would benefit the patient. Physicians

also should advocate for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy. Quality improvement rather than cost containment should be the primary determinant for formulary exclusions. In order to be cost efficient, however, physicians should select the lowest cost medication of equal efficacy for their patients.

(3) Physicians should advocate that limits be placed on the extent to which health care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians should not be made to feel that they jeopardize their compensation or participation in a health care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, which should be calculated according to the practices of a sizeable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Prescriptions should not be changed without the physician's knowledge and authorization. This affords the physician the opportunity to discuss the change with the patient.

(4) Physicians should encourage health care plans to develop mechanisms to educate and assist physicians in cost-effective prescribing practices, including the availability of clinical pharmacists. Such initiatives are preferable to financial incentives or pressures by health care plans or hospitals, which can be ethically problematic.

(5) Physicians should advocate that methods to limit prescription drug costs within health care plans in which they participate be disclosed to patients. In particular, they should encourage health care plans to inform patients upon enrollment concerning:

(a) the existence of formularies,
(b) provisions for cases in which the physician prescribes a drug that is not included in the formulary,
(c) incentives or other mechanisms used to encourage formulary compliance by physicians,
(d) relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary.

If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial drug to the patient, so that the patient can consider whether to obtain the medication out-of-plan. Under circumstances in which the health care program will not subsidize the drug, physicians should help patients by identifying alternative forms of financial assistance, such as those available through pharmaceutical companies' assistance programs.

Issued June 1996 based on the report "Managed Care Cost Containment Involving Prescription Drugs," adopted June 1995; updated June 2002

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BUSINESS

Doctors Net Billions From Drug Firms

Companies Paid at Least $3.5 Billion in Last Five Months of 2013

By PETER LOFTUS
Updated Sept. 30, 2014 7:29 p.m. ET

Drug and medical-device companies paid at least $3.5 billion to U.S. physicians and teaching hospitals during the final five months of last year, according to the most comprehensive accounting so far of the financial ties that some critics say have compromised medical care.

The figures come from a new federal government transparency initiative. The 2010 Affordable Care Act included a provision dubbed the Sunshine Act, which requires manufacturers of drugs and medical devices to disclose the payments they make to physicians and teaching hospitals each year for services such as consulting or research. The Centers for Medicare and Medicaid Services compiled the records into a database posted online Tuesday, though the agency said that about 40% of the payment information won't identify the recipients because of data problems.

The database revealed some eye-popping totals, such as the $122.5 million paid by Roche Holding AG's Genentech unit to City of Hope medical center in Duarte, Calif., as royalties on sales of several products including blockbuster cancer treatments Herceptin and Avastin.

Genentech licensed patents from City of Hope based on research the medical center conducted in the early 1980s. The company said that excluding the City of Hope royalties, about 85% of the physician payments it reported to CMS were focused on drug research. City of Hope said the royalties are allocated to the inventors and to support continuing research.

The Centers for Medicare and Medicaid Services posted a database online showing payments made by makers of drugs and medical devices to physicians and teaching hospitals. *BLOOMBERG*

Some doctors disputed details of the payment data. The database shows John LeDonne, a surgeon from Baltimore, as having received about $78,200 in payments for food and beverage for the five-month period from medical-device maker Teleflex Inc.

Dr. LeDonne acknowledged he performs paid consulting work for health-care companies including Teleflex, but that he rarely received free meals. He said the total payment amount was in the right "ballpark," but should not have been classified in the food-and-beverage category.

"They certainly did not give me $78,000 in lunch money," Dr. LeDonne said in an interview. "Lunch is not a big deal in most parts of my life." Teleflex didn't immediately respond to requests for comment.

The push for greater transparency was driven by concerns that doctors' prescribing decisions are tainted by the money and gifts they receive each year from companies. Supporters expect the transparency initiative to provide useful information to patients about the relationships their doctors have with industry and to curb the influence of payments on medical care.

"The financial relationships between doctors and drug companies and medical-device companies are a source of conflicts of interest," said Allan Coukell, director of the Pew Prescription Project, which has supported the Sunshine Act. "They have the potential to influence the care that patients get and so they're a matter of interest both to individual consumers and to policy makers."

CALLS FOR TRANSPARENCY

- The government wants to have more disclosure about payments made to doctors and teaching hospitals. (http://cms.gov/openpayments/)
- U.S. physicians have faced scrutiny over gifts received from companies. (http://online.wsj.com/news/articles/SB10001424127887323455104579014812178937016)
- Some drug makers have reduced their payments to doctors. (http://online.wsj.com/news/articles/SB10001424127887324695104578414530096553710)
- Does the Open Payments database distort what doctors receive for research? (http://blogs.wsj.com/pharmalot/2014/09/30/does-the-open-payments-database-distort-doc-payments-for-research/?)
- CMS is asked to drop some payments from sunshine database. (http://blogs.wsj.com/pharmalot/2014/09/16/cms-asked-to-eliminate-more-payments-from-sunshine-database/)

Companies have defended their payments to physicians as necessary to conduct research and communicate how products should be used. "I welcome these disclosures," said John C. Lechleiter, chief executive of drug maker Eli Lilly & Co., which was mandated to report physician payments on its website as part of a 2009 settlement with the government over illegal-marketing allegations. "We believe the payments that are spelled out in these reports can be entirely justified and in fact are critical for us to be able to discover and develop medicines and effectively communicate their value."

The payments and so-called transfers of value to an estimated 546,000 doctors and 1,360 teaching hospitals include such items as free meals that company sales representatives bring to physicians' offices, fees paid to doctors to speak about a company's drug to other doctors at restaurants, compensation for clinical trial research and consulting fees.

Some doctors have earned tens of thousands of dollars annually from drug companies by flying to various cities to give paid speeches, while some surgeons have received even larger amounts from medical-device makers, partly from royalties on products they helped develop.

Doctors have expressed concern about having their names attached to money paid by industry. Some have scaled back their interactions with industry because they know it will be reported publicly.

The information in the database is broken down by category of payment—separating out research from "general payments," which includes money paid for a range of things including consulting, travel, grants and entertainment, for instance. But some doctors are concerned the public presentation of the data will lack context that explains the possible value of the doctor's relationship with a company.

"Questions from confused patients are especially likely, given that the online database is not expected to offer much context for the financial interactions it reports between physicians and manufacturers of medical devices and drugs," the American Medical Association said. The association had asked CMS to delay publication of the payment data to give doctors more time to review the accuracy of the reports.

Among individual physicians, Stephen Burkhart was one of the top recipients of non-research payments from industry. The San Antonio orthopedic surgeon received $7.4 million in non-research payments or transfers of value for the five-month period, mostly from device manufacturer Arthrex Inc. for payments identified as "royalty or license."

Dr. Burkhart couldn't be reached for comment. Arthrex said in a statement that it has "financial relationships with a number of orthopedic surgeons and teaching hospitals," like many manufacturers, for their advice and expertise.

Chitranjan Ranawat, a New York orthopedic surgeon, received about $4 million in nonresearch payments or transfers of value, mostly from Johnson & Johnson's DePuy Synthes unit for "royalty or license," according to the database.

Dr. Ranawat couldn't be reached for comment. A J&J spokeswoman said the company works with surgeons and other professionals to develop products, and pays royalties to inventors holding patents.

Some drug and device companies including Lilly, Pfizer Inc. and GlaxoSmithKline PLC have been disclosing individual physician-payment records on their own websites for several years because of settlements of government investigations of their marketing practices.

Such company disclosures have shown that some companies have reduced spending on items such as speaking fees and meals in recent years. Some said they cut back on such items because they have reduced the size of their sales forces and have used other methods of communicating with doctors, such as online meetings.

The first batch of data released by CMS on Tuesday covers payments made from Aug. 1 to Dec. 31, 2013. Beginning next year, companies will report full-year data annually. Companies submitted the data to CMS earlier this year, using the so-called Open Payments portal. The agency has allowed physicians to register with the Open Payments system to get a preview of the payment records, before it went public, to allow time for them to dispute any reports they believed were inaccurate.

But it hasn't been a smooth process. First, CMS delayed the public reporting of the data by a year to give companies more time to prepare. The Open Payments online system has experienced technical problems, including a data mix-up that resulted in some doctors being linked to payment records for other doctors with the same surname. The preview function for doctors had a cumbersome registration process, some doctors said, and was taken offline at times in recent weeks.

The first batch of data is incomplete. CMS in August said it removed about one-third of the payment records from the physician-preview database because it said some of the state medical-license numbers that companies reported for doctors didn't match a database that the agency was using for verification, among other problems. CMS now is releasing those records but without identifying the physicians tied to them. It will update the database to include the physicians' names for those records next year. Also, CMS isn't immediately releasing payments related to proprietary research-and-development; those will be reported at a later date.

The agency's handling of the problematic records also has drawn criticism from companies, which said they reported the vast majority of data properly.

About $22 million in physician-payment records reported Eli Lilly for the five-month period of last year, for example, was removed from the physician-preview database, out of a total reported of about $85 million, said Ashish Kalgaonkar, senior director of Lilly's transparency reporting. "I'm very confident that my data is correct," Mr. Kalgaonkar said.

Industry and medical groups also have complained that CMS didn't offer advance information about how the data would be presented publicly.

"The rollout won't be perfect," Sen. Chuck Grassley (R., Iowa), a co-author of the Sunshine Act legislation, said in a written statement before Tuesday's release. "Some information will be withheld because CMS wanted to protect doctors from a small amount of reports that might be imprecise. But as the information is refined, the database will improve. It will become more complete as doctors, drug and device companies and CMS work to update and refine the information."

The new database may lend itself to a range of uses. A Justice Department spokeswoman said Tuesday the department may use the Open Payments data "to help assess the nature and extent of any financial relationships that exist between pharmaceutical and medical device manufacturers and prescribing physicians, and whether such relationships violate federal law."

One former Senate staffer who was closely involved in the effort to pass the Sunshine Act hopes the database will do some good. "This website will let patients ask a very important question: 'Is a relationship between my doctor and a drug company right for me?' It took six years of hard work to get this site together and, hopefully, it will help clean up medicine," said Paul Thacker, a former aide to Sen. Chuck Grassley (R-Iowa) who is now a fellow at the Safra Ethics Center at Harvard University. He said the "total amount of money is pretty eye popping."

—Joseph Walker, Ed Silverman and Tom McGinty contributed to this article.

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Local hospital, doctor named in lawsuit over fake surgical hardware

By Meredith Cohn
The Baltimore Sun

JULY 16, 2015, 7:21 PM

The University of Maryland's Baltimore Washington Medical Center is sending letters to about 250 spinal fusion patients who received hardware from a defunct California company accused of selling fake parts.

The Glen Burnie hospital is continuing to investigate whether any counterfeit parts were used in patients and sent the letters to "address any concerns." Officials said they've found no evidence yet its patients were affected.

A number of hospitals across the country, including Baltimore Washington Medical Center, have been sued by health insurers alleging the hospitals used the fake parts and overbilled for them. The suit also named one of the hospital's spinal surgeons, Dr. Randy Davis. Local law firms are also investigating and reaching out to patients.

The parts in question were distributed by a company called Spinal Solutions LLC, which was cited in 2012 by the U.S. Food and Drug Administration for quality control problems. The following year, the company recalled parts used in lower spine fusions, specifically saying that some had been distributed in Maryland.

In announcing the recall, the FDA said inadequacies in the parts "might result in product performance failures that could cause patient harm due to implant breakage, movement, or inadequate sterilization."

One local lawyer questioned why the recall didn't prompt hospitals that used the hardware to investigate earlier and notify patients there was a possibility that counterfeit hardware had been implanted.

"We've discussed this with numerous patients and all have questions about the health implications of potentially having these unapproved parts in their bodies," said Judson H. Lipowitz, who manages the injury and wrongful-death practice of Azrael, Franz, Schwab & Lipowitz.

The Towson firm and the Law Firm of Peter G. Angelos began advertising for patients after seeing stories about Spinal Solutions, which went out of business after the recall. None of the patients who've responded to Lipowitz's firm have received a letter from the hospital yet, he said, adding that sending them is a good step.

The case highlights the growing problem of counterfeit medical devices and drugs that national and international regulators have sought to stem, and raises questions about how to best protect consumers.

"Shadowy product makers are trying to worm their way into the supply chains," said James Quiggle, spokesman for the Coalition Against Insurance Fraud, an industry and consumer watchdog that has been monitoring the Spinal Solutions case.

"The junk is implanted in people and can cause permanent harm," he said. "Some luckless patients must face lifetimes of pain and disability."

Quiggle said the global problem calls for more cooperation among regulators here and overseas where many devices are made. He said hospitals also have a responsibility to police the supply chain, and one "red flag" is financial arrangements doctors have with equipment and drug makers.

Such arrangements, however, are not uncommon and hospitals have said they can lead to advances in medicine. The U.S. Centers for Medicaid and Medicare Services recently reported $6.5 billion in payments to doctors from drug and device makers for consulting, royalties and other services.

The insurers' suit alleges that doctors, including Davis at Baltimore Washington Medical Center, were given lucrative "sham" consulting contracts in exchange for bringing business to Spinal Solutions.

In the lawsuit, filed in February and unsealed in May, Davis is accused of accepting $458,962 in payments, largely in consulting fees. In return, the suit said, the hospital bought in excess of $1 million of implantable hardware from Spinal Solutions delivered by private aircraft.

The suit alleges that there were similar arrangements with doctors in California, Texas, Wisconsin and Nevada and that their hospitals were complicit. In all, it named 17 hospitals and 15 doctors as well as Spinal Solutions and other companies.

Davis, a board-certified orthopedic surgeon in the hospital's spine and neuroscience center, would not comment because of the pending lawsuit, according to Karen Lancaster, a spokeswoman for the University of Maryland Medical System, which owns the hospital.

Attorneys for the insurers who filed the suit did not respond to a request for comment.

Baltimore Washington Medical Center began a review when officials heard of the civil complaint, covering the years from 2007 to 2012, Lancaster said.

"Our review is continuing, but we have found no evidence that the alleged non-FDA approved hardware was ever received or used in spinal surgeries" at the hospital, she said. "The hardware identified in the complaint is used in a very specific type of spine surgery; only a small percentage of patients who underwent spinal surgery at [the hospital] during this time period had this specific kind of surgery."

The suit said the fake screws and rods were "insidiously co-mingled" with real products used in spinal fusion surgery.

Real FDA-approved parts are made of titanium, rather than the stainless steel used in the first generation of hardware in the 1980s, and are not likely to fail, said Dr. Paul Asdourian, regional director of the spine program at MedStar North, who is not involved in the litigation.

If the screws and rods break or dislodge during the six weeks to six months it can take bones to fuse, the bones may not heal properly. That could lead to pain and more surgery, he said.

Patients have the procedure for several problems, including a fractured spine or a painful arthritic condition.

Asdourian said the number of spinal fusions a surgeon performs varies, but might average 75 to 100 a year. Not all require implants, and some surgeons use hardware from several suppliers, he said.

But, he acknowledged, telling a fake screw from a real one could be tough.

"It depends on how good the fake is," Asdourian said. "If it's done by a good machine shop, it may be difficult to tell. I try and use reputable companies and I know my reps, but you have to trust these people. ... If I noticed the screws looked different, I'd say something. If I noticed they broke in a couple of patients, I'd question it."

The World Health Organization, which formed a task force to stem the flow of counterfeit drugs and devices in 2006, said the scope of the problem is tough to gauge, though in 2010 it estimated about 8 percent of all devices on the market were fake.

In 2012, U.S. Customs & Border Protection reported that 9 percent of all its seizures, or 2,350 packages, were counterfeit drugs and medical devices. They were worth $83 million, and more than half came from China.

The FDA recently reported that about 40 percent of finished drugs and more than half of medical devices in the United States come from overseas, and the agency has stepped up inspections of foreign facilities. In June, the agency took action against 1,050 websites to stop selling illegal, unapproved and potentially dangerous medicines and devices.

The FDA would not confirm if it plans to take further action against Spinal Solutions.

The insurers' suit alleges fakes got through because the hospitals and doctors "willfully failed to ensure the material was genuine and FDA approved."

It says this "represented an opportunity to make money, without regard as to whether surgery was necessary... and more importantly, without regard to the safety, health and well-being of patients."

Local attorneys are just gathering information for now, seeking patients who had spinal surgery at Baltimore Washington Medical Center between 2007 and 2013 and their medical records.

"Right now we are just investigating and trying to get a client base and a look at their records to see if its true," said Jay Miller, an attorney with Angelos' firm.

"The universe is unknown at this point," Lipowitz said. "There were parts commingled in the supply chain. We don't know where this ends."

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DOLLARS FOR DOCTORS

We Found Over 700 Doctors Who Were Paid More Than a Million Dollars by Drug and Medical Device Companies

ProPublica has been tracking drug company spending on doctors since 2010. We just updated our database and found that companies are still paying private doctors huge sums for promotional talks and consulting.

by Charles Ornstein, Tracy Weber and Ryann Grochowski Jones, Oct. 17, 2019, 12 p.m. EDT

ProPublica is a nonprofit newsroom that investigates abuses of power. Sign up to receive our biggest stories as soon as they're published.

Back in 2013, ProPublica detailed what seemed a stunning development in the pharmaceutical industry's drive to win the prescription pads of the nation's doctors: In just four years, one doctor had earned $1 million giving promotional talks and consulting for drug companies; 21 others had made more than $500,000.

Six years later — despite often damning scrutiny from prosecutors and academics — such high earnings have become commonplace.

More than 2,500 physicians have received at least half a million dollars apiece from drugmakers and medical device companies in the past five years alone, a new ProPublica analysis of payment data shows. And that doesn't include money for research or royalties from inventions.

More than 700 of those doctors received at least $1 million.

"Holy smokes," said Dr. Walid Gellad, an associate professor of medicine and health policy at the University of Pittsburgh, where he leads the Center for Pharmaceutical Policy and Prescribing. It is "quite striking" how much money doctors were earning from "other activities aside from patient care," he said.

To identify the latest pharma millionaires and other spending trends, ProPublica analyzed more than 56 million payments made from 2014 to 2018 — the first five full years of the federal Open Payments initiative, which requires companies to publicly disclose the payments as part of the 2010 Affordable Care Act.

Prescription Drugs With Top Spending on Doctor Payments

Here are the drugs for which pharmaceutical companies spent the most money paying doctors, per year, excluding research and royalty payments. The list does not include payments to teaching hospitals. Data for 2014-2016 is from a prior release of Dollars for Docs and any subsequent updates are not reflected.

2016	2017	2018
Xarelto $29.2M	**Xarelto** $25.1M	**Xarelto** $17.9M
Eliquis $18.8M	**Entresto** $18.7M	**Farxiga** $12.6M
Invokana $18.2M	**Jardiance** $17.1M	**Humira** $12.2M
Humira $15.2M	**Invokana** $16.6M	**Jardiance** $12.2M
Tresiba $14.5M	**Eliquis** $15.4M	**Keytruda** $11.7M
Toujeo $13.9M	**Farxiga** $14.8M	**Eliquis** $11.6M
Farxiga $13.5M	**Humira** $14.4M	**Repatha** $10.9M
Entresto $13.2M	**Aubagio** $13.1M	**Aubagio** $10.7M
Repatha $12.0M	**Repatha** $11.4M	**Entresto** $10.2M
Otezla $12.0M	**Keytruda** $11.3M	**Otezla** $10.2M
Viberzi $11.0M	**Otezla** $10.5M	**Dupixent** $9.90M
Aubagio $10.5M	**Trulicity** $9.67M	**Vraylar** $9.68M
Linzess $10.2M	**Tresiba** $9.46M	**Invokana** $9.06M
Trintellix $8.12M	**Victoza** $9.20M	**Trulicity** $8.99M
H.P. Acthar $8.10M	**Lemtrada** $8.78M	**Cosentyx** $7.95M
Latuda $8.00M	**Nuplazid** $8.52M	**Ozempic** $7.77M
Victoza $7.89M	**Trintellix** $8.13M	**Latuda** $7.57M
Keytruda $7.51M	**Linzess** $7.96M	**Aimovig** $7.54M
Vraylar $6.99M	**Viberzi** $7.85M	**Soliqua** $7.52M
Lemtrada $6.84M	**Latuda** $7.65M	**Tresiba** $7.37M

Credit: Moiz Syed/ProPublica. Source: ProPublica analysis of Open Payments data from the Centers for Medicare and Medicaid Services.

Some academics and physicians predicted that the exposure might cause companies to rethink making payments and doctors to rethink taking them. A flurry of studies matched the payment data with doctors' prescribing choices and found links between the payments and the products doctors chose.

But ProPublica's new analysis shows that the public reporting has not dampened the enthusiasm of the drug and medical device industry for having doctors deliver paid dinner talks and sponsored speeches or paying them to consult on products.

In fact, there has been almost no change in how much the industry is spending. Each year from 2014 to 2018, drug and medical device companies spent between $2.1 billion and $2.2 billion paying doctors for speaking and consulting, as well as on meals, travel and gifts for them. (These figures do not include research spending, but they do include royalties.)

Roughly the same number of doctors — more than 600,000 — received payments in any given year.

That consistency, some academics say, is conspicuous.

"It makes me wonder whether patients are using this information or whether physicians are even aware this information is out there," said Dr. Joseph Ross, a professor of medicine and public health at Yale who has studied pharmaceutical marketing. "It's almost like it's not happening."

Holly Campbell, a spokeswoman for the Pharmaceutical Research and Manufacturers of America, defended company payments to doctors. "It is not necessarily a negative that the numbers have remained generally flat over the past five years," she wrote in an email. "That statistic appears to be consistent with companies' belief that their interactions with

physicians have been and remain legitimate, even when subjected to sunshine."

ProPublica first delved into the world of drug company promotional campaigns in 2010 when it gathered the payments made by seven companies that were required to make them public as part of settlements in whistleblower lawsuits. The payments were published in a database called Dollars for Docs, which allowed anyone to look up a doctor and see if he or she received a payment.

Today, ProPublica is updating Dollars for Docs with the latest data from the federal government on all payments.

Among our findings:

Consistency Breeds Familiarity

Over the course of five years, 1 million doctors, dentists, optometrists, chiropractors and podiatrists received at least one payment, most often a meal, from a company. Of those practitioners, more than 323,000 received at least one payment every year. About 240,000 received a payment in only one year. And the rest received payments in more than one year but in fewer than five.

For context, there are about 1.1 million doctors in the United States.

Dr. Aaron P. Mitchell, a medical oncologist and health services researcher at Memorial Sloan Kettering Cancer Center, said his research has shown that when doctors interact more consistently with a drug company they are more likely to prescribe that company's cancer drug. The drug industry, Mitchell said, "knows that they need to cultivate relationships over more time, so that's what they're really trying to do. It's not just one drug meal. It's consistency."

Some Drugs Are Promoted Heavily Year After Year

Of the top 20 drugs with the most annual spending on doctors from 2014 to 2018, six made the list in each of the years: Invokana to treat type 2 diabetes, the blood thinners Xarelto and Eliquis, the antipsychotic Latuda, the immunosuppressive drug Humira and the multiple sclerosis drug Aubagio. Another three drugs were on the list for four years: Victoza to treat type 2 diabetes, psoriasis treatment Otezla and the cholesterol-lowering drug Repatha. (Research funding and royalties are not included.)

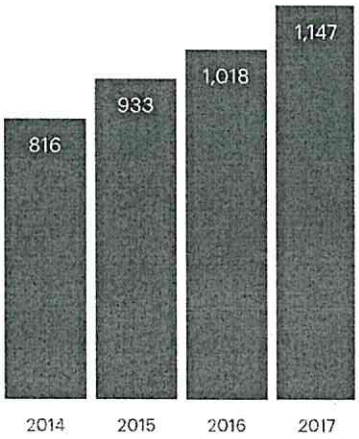
Xarelto topped the list in spending for four years, totaling more than $123 million in payments from 2014 to 2018. In March, its makers, Johnson & Johnson and Bayer AG, agreed to pay $775 million to settle about 25,000

lawsuits claiming that the companies had failed to warn patients that Xarelto could cause fatal bleeding.

In statements, J&J and Bayer have said that the allegations lacked merit and that Xarelto is safe and effective. They noted that six cases that went to trial were decided in their favor.

The Number of Big-Ticket Promotional Speakers Is Up More Than 30% in Five Years

The number of doctors who received $100,000 or more, by year, for services other than consulting, which typically means delivering promotional speeches.



Source: ProPublica analysis of Open Payments data from the Centers for Medicare and Medicaid Services.

Many drugs on the list are in categories where there is fierce competition. For example, seven of the top 20 in 2018 treat diabetes. And in most of the drug classes on the list, "there are more than one available drug — sometimes all with the same mechanism of action — indicated for the same condition selling for very high prices," Dr. Aaron Kesselheim, a professor of medicine at Harvard Medical School, said in an email.

According to GoodRx, a drug discount website, the average cash price of a month's supply of diabetes drugs Invokana, Jardiance and Farxiga is more than $600.

"Promotional spending is a major way that manufacturers in these situations distinguish themselves from each other — not by conducting comparative studies or by engaging in substantial price reductions," Kesselheim said.

ProPublica and a number of researchers have examined the types of drugs that prompt the highest payments. Ross, of Yale, and a colleague published an analysis in the British Medical Journal in 2017 that found that the "top promoted drugs were less likely than top selling and top prescribed drugs to be effective, safe, affordable, novel, and represent a genuine advance in treating a disease."

"Our findings suggest that pharmaceutical promotion should be met with healthy skepticism," the analysis concludes.

Prosecutors Say the Payments by Some Drug Companies Are Kickbacks, Despite the Transparency of Open Payments

There is a perception among many physicians, including some in academia, that drug company payments are fairly benign — a moonlighting gig that educates other doctors about important medications. But since ProPublica began looking at physician payments, one drugmaker after another has paid tens, or even hundreds, of millions of dollars to resolve allegations of improper, or illegal, marketing tactics.

In fact, drug company whistleblowers and federal prosecutors have said explicitly that in some cases the payments were actually bribes and kickbacks. And this behavior has continued despite tools like Dollars for Docs.

Here are some recent examples:

- **Insys Therapeutics**

  Spending: In 2014, the payment data shows, Insys Therapeutics spent $7.5 million promoting Subsys, a fentanyl spray for advanced cancer pain, making it one of the drugs with the most spending that year. Through 2018, the company's total spending on the drug had reached $17.6 million.

  Prosecutors say: Insys paid doctors to speak about Subsys to other physicians during "educational lunches and dinners," according to a Justice Department press release, from August 2012 to June 2015. The meals "were actually used as a vehicle to pay bribes and kickbacks to targeted practitioners in exchange for increased Subsys prescriptions to patients and for increased dosage of those prescriptions."

  Penalty: This June, Insys agreed to plead guilty to five counts of mail fraud, pay a $2 million fine and forfeit $28 million. It also agreed to pay $195 million to settle a separate whistleblower case. At least eight company executives have now been convicted of crimes relating to the illegal marketing of the drug. Insys has said it completely restructured its operations, hired new leaders and has filed for bankruptcy protection.

- **Avanir Pharmaceuticals**

  Spending: From 2014 to 2018, Avanir spent nearly $22 million on its drug Nuedexta, which treats pseudobulbar affect, or uncontrollable laughing or crying.

Prosecutors say: An Avanir employee reported that one doctor at a long-term care facility, who was also a paid speaker for Nuedexta, put "entire units" of patients on Nuedexta. Another doctor at the facility, which had a number of dementia patients, routinely stopped the Nuedexta, only to have the first doctor restart it, according to a Department of Justice press release.

Penalty: In September, the company agreed to pay more than $108 million to resolve criminal and civil allegations that it paid kickbacks to doctors and marketed the drug for unapproved uses, including behaviors associated with dementia. In a statement, Avanir said it fully cooperated with investigators "and engaged in extensive remedial measures. The individuals listed in the resolution agreements are no longer Avanir employees."

Though relationships between drug companies and doctors continue, seemingly with little change, Kesselheim, of Harvard, said that the transparency "helps bring into light an area of the field that was in the shadows.

"Now we need to figure out what to do with this."

Filed under: Health Care

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Charles Ornstein oversees the Local Reporting Network, as well as ProPublica offices in the Midwest, the South, the Southwest and a unit operated with The Texas Tribune.

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SB 159_Gratuities and Incentives.pdf
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TESTIMONY OF SENATOR DELORES G. KELLEY

REGARDING SENATE BILL 159-HEALTH OCCUPATIONS-AUTHORIZED PRESCRIBERS-REPORTING OF FINANCIAL GRATUITIES OR INCENTIVES

BEFORE THE SENATE COMMITTEE ON EDUCATION, HEALTH AND ENVIRONMENTAL AFFAIRS

ON FEBRUARY 10, 2022

Mr. Chairman and Members:

Senate Bill 159 requires specified categories of authorized prescribers of drugs and devices to give private, but timely notice to their respective health occupation boards whenever the authorized prescriber accepts a financial gratuity or incentive in exchange for the promotion of products or services. This Bill includes a list of ten common forms of gratuities which manufacturers of drugs and medical devices commonly offer to promote their new products and/or devices. Senate Bill 159 takes no position on any particular offer or acceptance of a gratuity, but directs Maryland's various health occupation boards to develop regulations for systematic and private

reviews of gratuity notifications required to be submitted to the appropriate health occupation board in each instance.

The point of SB 159 is to empower Maryland's health occupation boards to develop regulations which ensure systematic, private review, as well as, appropriate responses to required notifications of gratuities already accepted by any of each board's roster of authorized prescribers.

The Bill sponsors and members of this important Senate Committee recognize that not all offers of gratuities are equal. The sponsors of SB 159 hope that highlighting the superfluous amounts which some (but not all) health care providers have accepted from either drug companies or from manufacturers, will be on record with the appropriate health occupation board, which can privately evaluate such notice so that where questionable, the occupation board can take appropriate action, as per its regulatory oversight.

While there is a national database requirement of relevance in the U.S (See Sec. 1128G. [42 U.S.C. 1320a-7h] (a) Transparency Reports), the resulting on-line

document is too massive (hundreds of thousands of entries) to be useful at a state or local level, and this on-line report focuses solely on physicians and not on any other category of health care practitioners.

The public reporting required by SB 159 would be Maryland-specific and would be a private report submitted, only when applicable, to the occupational board for each category of health care providers.

Attached to my written testimony are four very enlightening news articles which illustrate the excessive and unnecessary costs which result when health care practitioners accept unwarranted gratuities from manufacturers of medical hardware and/or from drug manufacturers.

"Doctors Net Billions from Drug Firms," *Wall Street Journal*, September 30, 2014;

"The AMA Code of Medical Ethics: Opinions on Physician's Relationships with Drug Companies and Duty to Assist in Containing Drug Costs," *Virtual Mentor: American Medical* Associations *Journal of Ethics*, April 2014;

"Local Hospital, Doctor Named in Lawsuit over Fake Surgical Hardware," ***The Baltimore Sun*****, July 16, 2015; and**

"Dollars for Doctors," *ProPublica*, October 17, 2019.

In light of all of these considerations, I humbly ask for your expeditious support of SB 159 with my amendment to add Senator Joanne Benson as a co-sponsor.

transparency reports.pdf
Uploaded by: Delores Kelley
Position: FAV

TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS

SEC. 1128G. [42 U.S.C. 1320a-7h] (a) TRANSPARENCY REPORTS.—

(1) PAYMENTS OR OTHER TRANSFERS OF VALUE.—

(A) IN GENERAL.—On March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

(i) The name of the covered recipient.

(ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.

(iii) The amount of the payment or other transfer of value.

(iv) The dates on which the payment or other transfer of value was provided to the covered recipient.

(v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) cash or a cash equivalent;

(II) in-kind items or services;

(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or

(IV) any other form of payment or other transfer of value (as defined by the Secretary).

(vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) consulting fees;

(II) compensation for services other than consulting;

(III) honoraria;

(IV) gift;

(V) entertainment;

(VI) food;

(VII) travel (including the specified destinations);

(VIII) education;

(IX) research;

(X) charitable contribution;

(XI) royalty or license;

(XII) current or prospective ownership or investment interest;

(XIII) direct compensation for serving as faculty or as a speaker for a medical education program;

(XIV) grant; or

(XV) any other nature of the payment or other transfer of value (as defined by the Secretary).

(vii) If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.

(viii) Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

(B) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE.—In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

(2) PHYSICIAN OWNERSHIP.—In addition to the requirement under paragraph (1)(A), on March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer or applicable group purchasing organization shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1877(c)) held by a physician (or an immediate family member of such physician (as defined for purposes of section 1877(a))) in the applicable manufacturer or applicable group purchasing organization during the preceding year:

(A) The dollar amount invested by each physician holding such an ownership or investment interest.

(B) The value and terms of each such ownership or investment interest.

(C) Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described in clauses (i) through (viii) of paragraph (1)(A), except that in applying such clauses, 'physician' shall be substituted for 'covered recipient' each place it appears.

(D) Any other information regarding the ownership or investment interest the Secretary determines appropriate.

(b) PENALTIES FOR NONCOMPLIANCE.—

(1) FAILURE TO REPORT.—

(A) IN GENERAL.—Subject to subparagraph (B) except as provided in paragraph (2), any applicable manufacturer or applicable group purchasing organization that fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $1,000, but not more

than $10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $150,000.

(2) KNOWING FAILURE TO REPORT.—

(A) IN GENERAL.—Subject to subparagraph (B), any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $1,000,000.

(3) USE OF FUNDS.—Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section.

(c) PROCEDURES FOR SUBMISSION OF INFORMATION AND PUBLIC AVAILABILITY.—

(1) IN GENERAL.—

(A) ESTABLISHMENT.—Not later than October 1, 2011, the Secretary shall establish procedures—

(i) for applicable manufacturers and applicable group purchasing organizations to submit information to the Secretary under subsection (a); and

(ii) for the Secretary to make such information submitted available to the public.

(B) DEFINITION OF TERMS.—The procedures established under subparagraph (A) shall provide for the definition of terms (other than those terms defined in subsection (e)), as appropriate, for purposes of this section.

(C) PUBLIC AVAILABILITY.—Except as provided in subparagraph (E), the procedures established under subparagraph (A)(ii) shall ensure that, not later than September 30, 2013, and on June 30 of each calendar year beginning thereafter, the information submitted

under subsection (a) with respect to the preceding calendar year is made available through an Internet website that—

(i) is searchable and is in a format that is clear and understandable;

(ii) contains information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(v), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(vi), and the name of the covered drug, device, biological, or medical supply, as applicable;

(iii) contains information that is able to be easily aggregated and downloaded;

(iv) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year;

(v) contains background information on industryphysician relationships;

(vi) in the case of information submitted with respect to a payment or other transfer of value described in subparagraph (E)(i), lists such information separately from the other information submitted under subsection (a) and designates such separately listed information as funding for clinical research;

(vii) contains any other information the Secretary determines would be helpful to the average consumer;

(viii) does not contain the National Provider Identifier of the covered recipient, and

(ix) subject to subparagraph (D), provides the applicable manufacturer, applicable group purchasing organization, or covered recipient an opportunity to review and submit corrections to the information submitted with respect to the applicable manufacturer, applicable group purchasing organization, or covered recipient, respectively, for a period of not less than 45 days prior to such information being made available to the public.

(D) CLARIFICATION OF TIME PERIOD FOR REVIEW AND CORRECTIONS.—In no case may the 45-day period for review and submission of corrections to information under subparagraph (C)(ix) prevent such information from being made available to the public in accordance with the dates described in the matter preceding clause (i) in subparagraph (C).

(E) DELAYED PUBLICATION FOR PAYMENTS MADE PURSUANT TO PRODUCT RESEARCH OR DEVELOPMENT AGREEMENTS AND CLINICAL INVESTIGATIONS.—

(i) IN GENERAL.—In the case of information submitted under subsection (a) with respect to a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or by an applicable manufacturer in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the procedures established under subparagraph (A)(ii) shall provide that such information is made available to the public on the first date described in the matter preceding clause (i) in subparagraph (C) after the earlier of the following:

(I) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

(II) Four calendar years after the date such payment or other transfer of value was made.

(ii) CONFIDENTIALITY OF INFORMATION PRIOR TO PUBLICATION.—Information described in clause (i) shall be considered confidential and shall not be subject to disclosure under section 552 of title 5, United States Code, or any other similar Federal, State, or local law, until on or after the date on which the information is made available to the public under such clause.

(2) CONSULTATION.—In establishing the procedures under paragraph (1), the Secretary shall consult with the Inspector General of the Department of Health and Human Services, affected industry, consumers, consumer advocates, and other interested parties in order to ensure that the information made available to the public under such paragraph is presented in the appropriate overall context.

(d) ANNUAL REPORTS AND RELATION TO STATE LAWS.—

(1) ANNUAL REPORT TO CONGRESS.—Not later than April 1 of each year beginning with 2013, the Secretary shall submit to Congress a report that includes the following:

(A) The information submitted under subsection (a) during the preceding year, aggregated for each applicable manufacturer and applicable group purchasing organization that submitted such information during such year (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to Congress after the date on which such information is made available to the public under such subsection).

(B) A description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year.

(2) ANNUAL REPORTS TO STATES.—Not later than September 30, 2013 and on June 30 of each calendar year thereafter, the Secretary shall submit to States a report that includes a summary of the information submitted under subsection (a) during the preceding year with respect to covered recipients in the State (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to States after the date on which such information is made available to the public under such subsection).

(3) RELATION TO STATE LAWS.—

(A) IN GENERAL.—In the case of a payment or other transfer of value provided by an applicable manufacturer that is received by a covered recipient (as defined in subsection (e)) on or after January 1, 2012, subject to subparagraph (B), the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer (as so defined) to disclose or report, in any format, the type of information (as described in subsection (a)) regarding such payment or other transfer of value.

(B) NO PREEMPTION OF ADDITIONAL REQUIREMENTS. —Subparagraph (A) shall not preempt any statute or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information—

(i) not of the type required to be disclosed or reported under this section;

(ii) described in subsection (e)(10)(B), except in the case of information described in clause (i) of such subsection;

(iii) by any person or entity other than an applicable manufacturer (as so defined) or a covered recipient (as defined in subsection (e)); or

(iv) to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

(C) Nothing in subparagraph (A) shall be construed to limit the discovery or admissibility of information described in such subparagraph in a criminal, civil, or administrative proceeding.

(4) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Services on the implementation of this section.

(e) DEFINITIONS.—In this section:

(1) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term "applicable group purchasing organization" means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or

medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(2) APPLICABLE MANUFACTURER.—The term "'applicable manufacturer" means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(3) CLINICAL INVESTIGATION.—The term "clinical investigation" means any experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

(4) COVERED DEVICE.—The term "covered device" means any device for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(5) COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term "covered drug, device, biological, or medical supply" means any drug, biological product, device, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(6) COVERED RECIPIENT.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term "covered recipient" means the following:

(i) A physician.

(ii) A teaching hospital.

(B) EXCLUSION.—Such term does not include a physician who is an employee of the applicable manufacturer that is required to submit information under subsection (a).

(7) EMPLOYEE.—The term "employee" has the meaning given such term in section 1877(h)(2).

(8) KNOWINGLY.—The term "knowingly" has the meaning given such term in section 3729(b) of title 31, United States Code.

(9) MANUFACTURER OF A COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term "manufacturer of a covered drug, device, biological, or medical supply" means any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

(10) PAYMENT OR OTHER TRANSFER OF VALUE.—

(A) IN GENERAL.—The term "payment or other transfer of value" means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.

(B) EXCLUSIONS.—An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

(i) A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100. For calendar years after 2012, the dollar amounts specified in the preceding sentence shall be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

(ii) Product samples that are not intended to be sold and are intended for patient use.

(iii) Educational materials that directly benefit patients or are intended for patient use.

(iv) The loan of a covered device for a shortterm trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

(v) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(vi) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

(vii) Discounts (including rebates).

(viii) In-kind items used for the provision of charity care.

(ix) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c)).

(x) In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

(xi) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.

(xii) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

(11) PHYSICIAN.—The term "physician" has the meaning given that term in section 1861(r).

Due to a scheduled technical upgrade, you may experience a temporary loss of access to our website between Friday, February 26, 11:00 p.m. and Saturday, February 27, 11:00 p.m.. We apologize for any inconvenience.

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February 8, 2022

To: The Honorable Paul G. Pinsky
Chair, Education, Health and Environmental Affairs Committee

From: The Office of the Attorney General's Health Education and Advocacy Unit

Re: Senate Bill 159 (Health Occupations – Authorized Prescribers – Reporting of Financial Gratuities or Incentives): Support

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) supports Senate Bill 159 which would add to the ability of Maryland's health occupations boards to protect patients from conflicts of interest that adversely influence prescribing practices. The bill would require each authorized prescriber who receives a financial gratuity or incentive from a pharmaceutical distributor or manufacturer to file a financial disclosure form with the health occupations board that licenses the authorized prescriber within 30 days after the financial gratuity or incentive is received. The information disclosed on the form may only be used to audit, investigate, or take disciplinary action against the authorized prescriber, and may not be made public. A health occupations board may impose a fine of up to $1,000 per violation if an authorized prescriber willfully fails to file a financial disclosure form.

The editorial board of a leading medical journal, JAMA, has stated that a conflict of interest exists "when professional judgement concerning primary interest such as patient's welfare or validity of research *may be* influenced by a secondary interest such as financial gain." (italics added). *See* Conflicts of Interest Theme Issue, Audio Editorial Summary. JAMA. 2017;317(17):1707-1709. doi:10.1001/jama.2016.13108.

In an ethics opinion on the topic of financial gratuities and incentives, the American Medical Association (AMA) stated "[a]ny gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value," and "[i]ndividual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads)," but otherwise warned against many types of

financial gratuities and incentives used by the pharmaceutical industry to influence prescribing practices. https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-physicians-relationships-drug-companies-and-duty-assist-containing/2014-04

With regard to the prescribing of all prescription drugs, we believe it is important for Maryland's health occupations boards to receive these reports in order to know when it is appropriate to audit and investigate a licensee's prescribing practices. The act of filing reports in and of itself seems to influence some prescribers to stop accepting financial gratuities or incentives, according to *Trends in Industry Payments to Medical Oncologists in the United States Since the Inception of the Open Payments Program, 2014 to 2019* :|

"In a study on industry payments received by oncologists following the [Physician Payments Sunshine Act], oncologists became less likely to receive industry payments, but the overall value of the payments increased. Over time, medical oncologists receiving lower-value payments (<$10 000) accepted smaller amounts and those receiving higher-value payments (>$10 000) accepted larger amounts. This indicates a consolidation of physicians receiving industry payments to a small number of oncologists accepting high payment values.

We would hope to learn that not many prescribers in Maryland accept financial gratuities and incentives with more than minimal value. If that is not the case, health occupations boards need to know and would have the disclosures in egregious cases, allowing appropriate action. We can see no good reason why any board would want to blind themselves to this data which would further their function of protecting patients in Maryland.

We ask the committee for a favorable report.

cc: Sponsor

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Position: FWA

Maryland

Board of Physicians

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

Damean W.E. Freas Board Chair – Christine Farrelly, Executive Director
4201 Patterson Avenue, Baltimore MD 21215 Phone: 410-764-4777; Email: mbpmail.rcn.com

2022 SESSION
POSITION PAPER

BILL NO.:	**SB 159 – Health Occupations – Authorized Prescribers – Reporting of Financial Gratuities or Incentives**
COMMITTEE:	**Education, Health, and Environmental Affairs**
POSITION:	**Support with Amendments**

TITLE: **Health Occupations – Authorized Prescribers – Reporting of Financial Gratuities or Incentives**

BILL ANALYSIS: Requires authorized prescribers to report all financial gratuities or incentives received from pharmaceutical distributors or manufacturers to file a disclosure form with the relevant health occupations board within 30 days.

POSITION & RATIONALE:

The Maryland Board of Physicians (the Board) is submitting this letter of support with amendments for Senate Bill (SB) 159 – Health Occupations – Authorized Prescribers – Reporting of Financial Gratuities or Incentives.

The Board currently licenses and regulates physicians and physician assistants, both of whom have prescriptive authority and who would be required to submit financial disclosures under SB 159. The Board is also the state agency that would be responsible for investigating a complaint that a physician or a physician assistant was inappropriately prescribing drugs or devices due to a financial conflict of interest.

Any information that could reveal a potential conflict of interest could prove useful in a Board investigation. However, the information being reported under SB 159 is already publicly available. Section 6002 of the Affordable Care Act, also known as the Physician Payments Sunshine Act, requires all manufacturers and distributors of medical products to disclose to the Centers for Medicare and Medicaid Services ("CMS") all payments or financial incentives made to physicians or teaching hospitals. This information is available online in a searchable database known as the CMS OpenPayments database. Since its implementation, the OpenPayments database has also expanded to include other provider types with prescriptive authority, including physician assistants. Creating a separate state requirement for authorized prescribers to report this data would be duplicative and unnecessary.

All Board investigations are initiated by complaints. Any complaint received by the Board receives a full and thorough investigation. However, the Board appreciates that many patients may be unaware that their physician has received financial gratuities or incentives from pharmaceutical companies, or that they can visit the CMS website to find this information, which in turn could prevent complaints from being filed. Therefore, the Board proposes including this information on the public practitioner profile pages, as is currently done with medical malpractice information. This change would make the information more publicly accessible and facilitate complaints and investigations without introducing a costly and duplicative secondary reporting requirement.

Therefore, the Board recommends striking the language found on page 2, line 19 through page 3, line 9. In addition, the Board recommends adding language to Health Occupations Article § 14-411.1(c) to include links to the CMS OpenPayments database.

Thank you for your consideration. For more information, please contact Matthew Dudzic, Health Policy Analyst, Maryland Board of Physicians, 410-764-5042.

Sincerely,

Damean W. E. Freas, D.O.
Chair, Maryland Board of Physicians

The opinion of the Board expressed in this document does not necessarily reflect that of the Maryland Department of Health or the Administration.

SB 159 Health Occupations- Authorized Prescribers-
Uploaded by: Erin Dorrien
Position: UNF

Maryland
Hospital Association

February 10, 2022

To: The Honorable Paul G. Pinsky, Chair, Senate Education, Health & Environmental Affairs Committee

Re: Letter of Concern - Senate Bill 159 - Health Occupations - Authorized Prescribers - Reporting of Financial Gratuities or Incentives

Dear Chair Pinsky:

On behalf of the Maryland Hospital Association's (MHA) 60 member hospitals and health systems, we appreciate the opportunity to comment on Senate Bill 159. The Affordable Care Act requires the Centers for Medicare & Medicaid Services (CMS) to collect information from manufacturers and group purchasing organizations regarding their financial relationships with physicians and hospitals. In addition, the federal Physician Payments Sunshine Act requires manufacturers of drugs, medical devices, biological, and medical supplies covered by Medicare, Medicaid, and the State Children's Health Insurance Program to collect and track all financial relationships with physicians and teaching hospitals and report these data to CMS.

The goal of these existing laws is to increase the transparency of financial relationships between health care providers and pharmaceutical manufacturers and to uncover potential conflicts of interest. The federal Open Payments program collects this information and makes it available via the CMS website. Under the law, manufacturers and group purchasing organizations report consulting fees, fees for serving as faculty or as a speaker at an event other than a continuing education program, honoraria, gifts, entertainment, food and beverage, travel and lodging, education, research, charitable contributions, and more. Federal law rightfully puts the reporting onus on manufacturers and group purchasing organizations because they are the ones making the payments.

SB 159 creates duplicative reporting requirements and is unnecessary as these arrangements are already made transparent by the federal government. Furthermore, this legislation increases regulatory burden on the already under resourced health occupations boards.

For these reasons we respectfully request an *unfavorable* report on SB 159.

For more information, please contact:
Erin Dorrien, Vice President, Policy
Edorrien@mhaonline.org

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Position: INFO

Maryland
Board of Nursing
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

February 10, 2022

The Honorable Paul G. Pinsky
Chair, Senate Education, Health, and Environmental Affairs Committee
2 West Miller Senate Office Building
Annapolis, MD 21401-1991

RE: SB 159 – Health Occupations – Authorized Prescribers – Reporting of Financial Gratuities or Incentives – Letter of Information with Amendments

Dear Chair Pinsky and Committee Members:

The Maryland Board of Nursing (the Board) respectfully submits this letter of information with amendments for Senate Bill (SB) 159 – Health Occupations – Authorized Prescribers – Reporting of Financial Gratuities or Incentives. This bill requires each authorized prescriber who receives a financial gratuity or incentive from a pharmaceutical distributor or manufacturer to file a disclosure form with a certain health occupations board within a certain period of time.

An Advanced Practice Registered Nurse (APRN) is a nurse who has met advanced educational and clinical practice requirements to provide and coordinate patient care in a number of healthcare settings. APRNs are independent providers who hold at least a Master's degree, in addition to a Registered Nurse (RN) license. Their scope of practice allows them to treat and diagnose illnesses, advise the public on health issues, manage chronic diseases, and engage in continuous educational efforts.

The state of Maryland recognizes four (4) APRN disciplines: Certified Registered Nurse Practitioner (CRNP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist (CRNA), and Certified Nurse Midwife (CNM). Pursuant to the Annotated Code of Maryland, Health Occupations Article (Health Occ.) Title 8, CRNPs and CNMs are currently authorized to prepare, prescribe, and dispense medications[1]. It has also come to the Board's attention that legislation being introduced in the 2022 legislative session would authorize an expansion of prescriptive authority to CRNAs and CNSs[2,3]. The Board respectfully submits Amendment #1 to expand the definition of an authorized prescriber to encompass multiple sections of Title 8.

The Public Information Act (PIA)[4], specifically General Provisions (GP) § 4-333, requires the Board to disclose to the public a final determination of disciplinary action, only if the Board

[1] Title 8 sections include: Section 8-101 Definitions; 8-508 Preparation and Dispensing of Drugs by Nurse Practitioners; and Section 8-601 Practice Nurse Midwifery Defined.
[2] Senate Bill 312. Health Occupations – Nurse Anesthetists – Drug Authority and Collaboration.
[3] Senate Bill 513. Health Occupations – Clinical Nurse Specialists – Prescribing Authority.
[4] Maryland Public Information Act Manual (Occupational and Professional Licensing Records 3-21). https://www.marylandattorneygeneral.gov/OpenGov%20Documents/Chapter3.pdf

determines that a licensee was guilty of unfair or illegal practice. The Board believes the publication of this information to be pertinent to the public's safety, health, and wellbeing. Additionally, sanctions imposed for disciplinary action vary among each of the health occupations boards. It should be the responsibility of each Board to determine the type of disciplinary action necessary. The Board respectfully submits Amendment #2 and Amendment #3 to reflect current disciplinary practices.

For the reasons discussed above, the Board of Nursing respectfully submits this letter of information with amendments for SB 159.

For more information, please contact Iman Farid, Health Policy Analyst, at (410) 585 – 1536 (iman.farid@maryland.gov) or Rhonda Scott, Deputy Director, at (410) 585 – 1953 (rhonda.scott2@maryland.gov).

Sincerely,

Gary N. Hicks
Board President

Amendment #1. On page 1. Section 1-227. Lines 21 – 22. Add:
(2) "AUTHORIZED PRESCRIBER" MEANS ANY LICENSED DENTIST, LICENSED PHYSICIAN, LICENSED PODIATRIST, ADVANCED PRACTICE **REGISTERED** NURSE WITH PRESCRIPTIVE AUTHORITY UNDER **[**§ 8–508 OF THIS ARTICLE,**]** **TITLE 8** OR ANY OTHER INDIVIDUAL AUTHORIZED BY LAW TO PRESCRIBE PRESCRIPTION OR NONPRESCRIPTION DRUGS OR DEVICES.

Amendment #2. On page 3. Section 1-227. Line 3. Add:
(2) MAY NOT BE DISCLOSED TO THE PUBLIC **EXCEPT AS PART OF A FINAL DISCIPLINARY ORDER.**

On page 3. Section 1-227. Lines 6 – 7.
(D) IF AN AUTHORIZED PRESCRIBER WILLFULLY FAILS TO FILE A FINANCIAL DISCLOSURE FORM AS REQUIRED BY SUBSECTION (B) OF THIS SECTION, THE HEALTH OCCUPATIONS BOARD MAY **PURSUE ANY DISCIPLINARY ACTION AUTHORIZED UNDER THE APPLICABLE PRACTICE ACT OR** IMPOSE A FINE NOT TO EXCEED $1,000 PER VIOLATION.

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