

The Abell Report

What we think about, and what we'd like you to think about

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ABELL SALUTES:
Arundel Habitat For Humanity
for providing affordable housing
to the McCulloughs of the world
and their “work and prayer”
formula that makes it all happen.

On a cold, below-freezing day in February 2007, 37-year-old Raymond McCullough (who is a salesman with K-Mart), his wife, Tori and their two daughters, Amari (11) and Narian (7) stood at the door of the end of row house on Jack Street in Brooklyn (Baltimore City), in stunned disbelief. Two years ago they had begun the journey that took them to this day: a home of their own—lovely, fully-furnished and functional two stories, with modern day amenities; living room and kitchen downstairs, three bedrooms upstairs, comparable to any home its size in the suburbs—at a monthly cost approximately \$800 a month less than market rate. No wonder the McCulloughs’ stared at their new home in disbelief that long-ago day in February 2007.

The McCullough’s story is one that leads through years of uncertain living, first in Annapolis, then in Glen Burnie, with violence and in housing that was unaffordable, to a home with Arundel Habitat For Humanity, a non-profit that creates affordable housing through renovation, new construction, and sweat equity, and sells the properties at no interest to low income families living in substandard and inadequate housing in the Brooklyn and Curtis Bay communi-

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Conflict-of-Interest Policies in Clinical Care Among Baltimore’s Healthcare Systems

*In the Study: Johns Hopkins, University of Maryland, MedStar
“Change Is Needed: This is the moment...to promote reform.”*

By Lisa Patterson, M.Sc., Susan Chimonas, Ph.D., and David Rothman, Ph.D.
Institute on Medicine as a Profession, Columbia University

I. Introduction

In the spring of 2008, The Abell Foundation asked The Institute on Medicine as a Profession (IMAP) at Columbia University to analyze clinical care conflict-of-interest (COI) policies at Baltimore’s three largest health-care networks. Accounting for a majority of the city’s hospitals and physicians, they are: University of Maryland Medical Center, Johns Hopkins Medicine, and MedStar Health. IMAP’s goal was to analyze the policies’ strengths and weaknesses by comparing them to each other and to the best practices drawn from IMAP’s previous research on academic medical-center guidelines.¹

Over the past several years, conflict-of-interest policies governing the relationships between physicians and the pharmaceutical and device industries have undergone dramatic change. Reflecting efforts to better manage the industries’ influence on health-care providers, the new policies give priority to scientific knowledge and patients’ best interests in treatment decisions. Helping to drive this change are two

important reports, the first published in 2006 by the American Board of Internal Medicine Foundation (ABIM) and IMAP; the second, released in 2008, came from the Association of American Medical Colleges (AAMC). Based on the recommendations of the two task forces, the reports agree on the precise guidelines that should be implemented to reduce or eliminate conflicts of interest in such areas as gifts, meals, free samples, vendor access, and continuing medical education (CME). Before 2006, the vast majority of academic medical-center (AMC) guidelines were lax. The task forces’ reports and the technical assistance provided by IMAP to various institutions have since promoted implementation of more rigorous policies.

At least one-quarter of AMCs now have exemplary policies and another half are working to improve their guidelines.² (See Appendix A for IMAP’s Exemplary Policies.) Boston University; the Universities of Massachusetts, Pennsylvania, Pittsburgh, Michigan, and Wisconsin; and the entire University of California system, among others, have adopted strict policies that minimize or

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eliminate the potential for conflicts of interest between their physicians and industry representatives.

Supporting these changes is a considerable body of research indicating that payments, gifts, honoraria, and meals provided to physicians by the pharmaceutical and device industries inappropriately influence physicians' prescribing practices. The data show conclusively that, consciously or not, physicians who receive gifts feel an obligation to reciprocate to the gift-giver. Pharmaceutical and device manufacturers understand all too well how this chain of influence works, which is why regulation is essential.



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The pharmaceutical companies have recognized the changed circumstances and are deemphasizing direct marketing to physicians and staff. In January 2009, the revised code of ethics from the drug industry's trade group, Pharmaceutical

Research and Manufacturers of America (PhRMA), took effect. The code is voluntary and not enforced by PhRMA. Its recommendations, nevertheless, would eliminate gift-giving to physicians by industry representatives and place further restrictions on marketing practices (e.g., meals in restaurants are prohibited but vendors are still permitted to bring food to physicians and staff).³ However, the new code does not penetrate the core of industry influence. Speakers' bureaus, honoraria, CME funding, and research grants are some of the many areas of policy that are unchanged in the code and remain permissive.

The level of transparency in physician-industry relationships is also increasing. Pharmaceutical and device manufacturers' payments to individual physicians and grants to health-care organizations are becoming open to public scrutiny. Eli Lilly, for example, is providing quarterly reports on its grants and charitable contributions to health-care organizations and will shortly begin disclosing its payments to physicians. As a result of a deferred prosecution agreement, several device manufacturers, including Stryker Corporation, Zimmer Holdings, and DePuy, have agreed to disclose their gifts and payments to physicians.

Notable, too, are recent laws in several states that require companies to report payments made to health-care providers. Maine, Minnesota, Washington D.C., West Virginia, and Vermont are the first states to require disclosure, with other states expected to follow. Senators Charles Grassley (R-Iowa) and Herbert Kohl (D-Wisconsin) have been at the forefront of change, demanding information from companies and organizations, and proposing legislation. In Sep-

tember 2007, the Senators introduced the Physician Payments Sunshine Act, which would require drug and device manufacturers to disclose to the Secretary of Health and Human Services gifts to prescribers in excess of \$500 annually. However, the bill only applies to companies with annual revenues more than \$100 million and does not account for the foundations and nonprofit organizations set up by manufacturers as less-obvious financial channels to health-care providers. Despite these concessions, lawmakers are determined to bring transparency to the health-care industry.⁴

In this environment of dramatic change, The Abell Foundation wanted to learn about policies in Baltimore. How are the city's health-care institutions responding to the new environment? Are they in the forefront of change, or resisting it? Can the citizens of Baltimore be assured that their health-care providers are acting in patients' best interests and not repaying obligations to industry? The following report is an effort to answer these questions.

II. Obtaining the Policies

Obtaining the conflict-of-interest policies from Baltimore's three largest health-care networks began in March 2008, with requests for participation in our study. The University of Maryland initially replied that its policies were under revision and, therefore, confidential; with new policies on the horizon, it became far more forthcoming. Johns Hopkins, too, was initially reluctant to share its policies, but then did so. Med-Star Health declined to participate early in the study; further communication proved fruitless.

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Baltimore Hospitals Clinical Care Conflict-of-Interest Policies: A Comparison with Best Practice Guidelines

	IMAP Best Practices	University of Maryland Medical School	Johns Hopkins Medicine	MedStar Health
Gifts	Prohibited both on-site and off, without exception.	Prohibited both on-site and off.	Gifts less than \$100 intended for direct patient use or for educational purposes are permitted.	Declined to participate in study.
Meals	Prohibited on-site without exception. Discouraged off-site.	Meals brought directly by reps are prohibited. Catering grants for CME events may be provided to the university foundation.	Meals are permitted for educational programs.	Declined to participate in study.
Drug Representative Access	Interactions between reps and staff restricted to meetings by appointment in nonpatient areas. Reps must check in upon arrival and wear identifying badges.	Rep are permitted by appointment only in nonpatient areas, after completing orientation, registering, and obtaining an ID badge.	Reps are permitted by appointment only, after first registering and obtaining an ID badge.	Declined to participate in study.
Samples	Staff prohibited from directly accepting samples. All samples must be managed by hospital pharmacy and not used by physicians or their families.	Free samples are prohibited in inpatient areas. Management of outpatient samples is the responsibility of individual departments.	Free samples are permitted in outpatient areas only and may be distributed by physicians.	Declined to participate in study.
Pharmacy & Therapeutics Committees	All committee members required to disclose. Those with financial ties must recuse themselves from making purchasing decisions.	All committee members and invited guests must disclose. Those with conflicts will be recused from voting on purchasing decisions.	No public policy.	Declined to participate in study.
CME and Support for Education	Mandatory incorporation of ACCME standards and full disclosure at CME events. Content must be reviewed by faculty for bias and all industry financial support must be distributed through a central fund.	All CME events must be sponsored directly or jointly by the university. Industry grants must be provided to and managed by the university foundation.	Industry-sponsored CME is permitted and must comply with ACCME standards. Individuals who control CME content must disclose relevant financial interests.	Declined to participate in study.
Consulting and Honoraria	Compensation for consulting must be at fair market value with clear deliverables outlined. Honoraria is strongly discouraged and requires prior approval before acceptance.	Consulting is permitted and requires prior approval and disclosure. Acceptance of honoraria requires prior approval and must be at fair market value.	Consulting by staff is permitted with prior approval. Staff is permitted to accept "reasonable" honoraria that is managed by the university.	Declined to participate in study.
Travel, Fellowships, and Scholarships	Industry funding must be directed to a central institutional fund that handles all disbursement. Funding directly to staff is prohibited and selection of recipients is at the discretion of the institution.	All educational and travel funds must be received and disbursed by the university foundation. Selection of recipients is under the discretion of faculty.	Staff may directly accept industry funding for travel and unrestricted education grants (e.g., scholarships and fellowships).	Declined to participate in study.
Ghostwriting	Ghostwriting is strictly prohibited. All authors must be duly credited and solely responsible for content.	Ghostwriting is prohibited. Policy encompasses oral presentations as well.	Ghostwriting is prohibited.	Declined to participate in study.
Speakers' Bureaus	Participation in speakers' bureaus is prohibited. For other industry speaking engagements, speaker must be solely responsible for content based on the best scientific evidence and must gain prior approval from department head to participate.	Participation in speakers' bureaus is prohibited.	Participation in speakers' bureaus is discouraged but permitted. Faculty must retain full control over content.	Declined to participate in study.

III. Analysis of Baltimore-Area Healthcare Networks

1. University of Maryland (“Maryland”)

The new University of Maryland policy sets a precedent for Baltimore’s health-care networks by enacting rigorous guidelines that promote professional accountability. It extends to all University of Maryland Medical School physicians and students at the UM Medical Center as well as its affiliates. It is distinct from the university’s primary conflict-of-interest policy governing all university faculty and staff, including its institutional review board for human experimentation. It focuses solely on how relationships between faculty and pharmaceutical and device industry representatives affect medical education and clinical care.⁵

The policy’s framework follows the outline laid out in IMAP’s best practices, with separate headings for gifts and meals, industry representative access, pharmaceutical samples, continuing medical education (CME), participation in industry-sponsored programs (such as speakers’ bureaus and educational events), scholarships and other educational funds (such as travel), and ghostwriting. Almost all of Maryland’s policies follow the strongest versions of IMAP’s best-practice recommendations, paying particular attention to regulating gifts, meals, CME, scholarships and travel, ghostwriting, and speakers’ bureaus. The attention Maryland pays to nearly all of IMAP’s policy areas demonstrates its recognition of the need to comprehensively manage conflicts of interest.

Like many such policies, Maryland’s begins with gifts and meals to individuals. Its policy on the subject is clear: No faculty member, staff personnel, or student may accept any gift from

industry, on-site or off. The qualifier on location indicates university officials’ acknowledgment of business conducted off campus and their desire to curb it. In addition, industry representatives are not permitted to bring food for staff or pay directly for physician meals at conferences. Maryland’s policy, however, does allow for industry to provide grants to providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) for catering at CME events. The policy also specifies that



The new University of Maryland policy sets a precedent for Baltimore’s health-care networks by enacting rigorous guidelines that promote professional accountability.



these grants must be directed to the University of Maryland Baltimore Foundation to be managed. Progressive policies such as this allow for only unrestricted industry grants for catering at CME events and mandate that funds must go to a central university account.

Maryland’s policy on vendor access outlines a detailed orientation and registration process. It explicitly states that all medical industry representatives must complete an electronic orientation before registering to obtain a badge during their visits to the medical center. Meetings between vendors and physicians are by appointment only and should be held in nonpatient areas. This eliminates the improper presence of vendors in patient waiting rooms and public

areas. Furthermore, Maryland’s explicit rules remove the enforcement burden from individual physicians and staff.

The university’s policy on drug samples bans free medication in inpatient areas. It does allow samples to be distributed in some outpatient areas and leaves management responsibilities to each department. The issue of free samples is a murky policy area for many AMCs. Physicians often want to provide free samples for needy patients or to win loyalty from all patients. Many health-care networks, like Maryland, understand that samples are marketing tools for industry representatives, gaining them access to physicians in order to promote new and expensive products when generics would often suffice. However, stronger policies direct all product donations to a central pharmacy for distribution, removing the pressure from physicians to accept and manage their samples. They also make certain that samples are recorded; not used for employees’ family and friends; not kept past their expiration; and distributed in accordance with appropriate safety measures.

Our study found that Maryland supports a rigorous, though not publicly available, conflict-of-interest policy regarding its pharmacy and therapeutics (P&T) committees. Considering the vast potential for problems when purchasing decisions are made by staff with financial ties to industry, a strong P&T policy is essential. Maryland’s policy requires annual disclosure by its committee members as well as rolling disclosures when new conflicts arise. Disclosure is required for all meeting attendees, including invited guests. Additionally, any person who requests a formulary addition must complete a conflict-of-interest statement. The recusal process allows members with conflicts to participate in discussions but bans them from voting. While Maryland’s policy is exemplary, an even better procedure is

not to appoint conflicted individuals to purchasing committees in the first place.

Maryland's policy on industry financing for CME requires that its activities meet ACCME standards, which is practice at virtually all AMCs. The policy permits the medical school to accept industry money for CME events provided that the money does not come with restrictions. However, Maryland's policy goes beyond the standard in its attempt to mitigate the influence of industry sponsorship by requiring that grants be directed to a central university account for management.⁶ This practice reduces industry influence by authorizing the university to control the disbursement of funds. The policy describes a detailed process for CME content that requires peer review by faculty, trained to identify scientific accuracy and bias.

The medical school is governed by the university's policy on consulting, which requires prior approval of outside professional activities. Additionally, reports disclosing payments for consulting must be submitted every semester by faculty to their department heads.⁷ Like Maryland's policy, the IMAP-ABIM recommendations require physicians to obtain permission from their department chairs before engaging in consulting activities. Considerations include: the type of consulting, the company offering the consulting work, the payment amount for services, the length of employment period, the physician's amount of time devoted to consulting activities, and the specific services requested by the company.

The medical school's policy for accepting honoraria is also rigorous: Faculty and staff are permitted to accept honoraria at "fair market value" with prior department approval.⁸ Although requiring department approval is forward-thinking, not requiring public disclosure limits meaningful accountability to patients. For honoraria, best practices

recommend department approval prior to acceptance and public disclosure. In addition, compensation should be by contract, at fair market value, with services limited to scientific and educational activities, not marketing.

Maryland's policy on industry-sponsored travel and educational grants



Many healthcare networks, like Maryland's, understand that samples are marketing tools for industry representatives, gaining them access to physicians in order to promote new and expensive products when generics would often suffice.



follows best-practice recommendations. Industry support for travel and education is accepted through a central university fund for management and disbursement.⁹ Under Maryland's policy, the selection of recipients is performed by the school, eliminating conflicts of interest that can arise when industry representatives choose the recipients for personal grants. Although there is no explicit mention of accepting only unrestricted grants, the University of Maryland Baltimore Foundation reviews and directs all funding agreements. It is important for AMCs to accept only industry grants that are unrestricted.

Ghostwriting is the practice of physi-

cians and researchers being listed as authors on articles actually written by industry employees. Maryland's policy explicitly prohibits the practice including "presentations of any kind, oral or written, to be ghostwritten by any party, from industry...or other source," an extension usually overlooked in many schools' policies. As one of the most obvious and undisputed policy prohibitions, ghostwriting is often overlooked in medical schools' conflict-of-interest guidelines. Maryland's acknowledgment and prohibition of the practice follows and even exceeds best-practice recommendations.

Speakers' bureaus are arrangements whereby companies train and pay physicians to speak on certain topics, typically using slides or other materials prepared by the company. These arrangements turn physicians into company sales representatives. While best practices recommend banning participation, most AMCs and health-care networks do not prohibit faculty participation on speakers' bureaus. Some have implemented modest restrictions, which include requiring speakers to gain prior approval from their department heads and mandating that speakers be solely responsible for their lecture content and slides. Maryland utilizes an excellent opportunity to bring its ghostwriting principles to its policy on speakers' bureaus by making the use of company slides tantamount to ghostwriting. Faculty, students, and trainees are prohibited from participating on speakers' bureaus, as well as any activity by which industry controls the content.

2. Johns Hopkins Medicine ("Hopkins")

The Johns Hopkins' conflict-of-interest policies are considerably less stringent than Maryland's.¹⁰ Indeed, they fall below best-practice standards as exemplified by such AMCs as Pennsylvania, Pittsburgh, and Stanford. The

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university has expressed a commitment to strengthening its policies and anticipates completing its revisions before the summer of 2009.

Hopkins permits physicians and staff to accept gifts less than \$100 in value from industry representatives for “educational purposes,” and leaves it to the recipients to determine a gift’s purpose and intent. At best, this policy presents the opportunity for patchwork decision making. At worst, it creates a situation for representatives and staff to exchange gifts that they deem, by any standard, to have “educational merit.” Additionally, the dollar threshold is not an aggregate amount but applies to individual gifts.

Hopkins permits industry representatives to provide meals for educational events and does not impose a dollar threshold. By allowing individual departments to accept unlimited food directly from industry representatives, the university is not held accountable for how much food its divisions and staff accept, from whom they accept it, or what obligations may follow. While leading AMCs have found the “feeding relationship” unacceptable, Hopkins has taken no steps to curtail it.

Hopkins’ policy on vendor access is strong. It requires all visiting representatives to schedule an appointment prior to arrival. They must enter through a designated entrance and register with security. They are to obtain an identification badge to be worn at all times on campus. Although representatives are permitted in public areas while moving through the hospital, they are prohibited from entering physician lounges or from being present at meetings and conferences. Appointments with representatives must be scheduled during weekday business hours, thereby limiting the amount of time physicians will set aside

to meet with representatives. The policy identifies industry representatives as they are—salespeople marketing their products, not educators.

Hopkins does not allow samples for inpatients but does allow them for outpatients, even some that are off formulary. It makes an effort to ensure patient safety by requiring samples to be registered and stored in the departments. However, any prescriber or pharmacist may distribute samples to patients because no central management system exists. As we noted in our analysis of Maryland’s samples policy, there are many advantages to a central pharmacy.¹¹



As one of the largest health-care providers in Baltimore, [Hopkins] wields enormous influence as a major purchaser of pharmaceuticals and medical devices.



Hopkins lacks a public policy to control conflicts of interest on P&T committees. As one of the largest health-care providers in Baltimore, it wields enormous influence as a major purchaser of pharmaceuticals and medical devices. Hopkins has informed us that its P&T committee, by its own procedure, does mandate disclosure and recusal. However, a public policy mandating such behavior would set a strong example of professionalism for its faculty, staff, and students.

Hopkins requires that its CME courses comply with ACCME standards. Any staff member in a position to

control CME activity content must submit a written disclosure of any relevant financial interest. Although useful, the policy leaves the matter of determining relevance to the individual. In addition, no procedure for peer review of the content is described, thus offering insufficient safeguards against industry influence on the selection of program topics. Of special note is Hopkins’ “Policy on the Identification and Resolution of Conflicts of Interest with Commercial Entities for Educational Planners and Faculty,” which categorizes potential conflicts according to their perceived threat of influence level. It states that an individual possessing multiple financial interests is “less likely to consciously or subconsciously influence the content of the activity in favor of one commercial entity...over another...for fear of losing or damaging a relationship with [the other companies].” It labels an individual with multiple financial interests as having “Level 1 Conflicts of Interests” and those with a single financial interest as “Level 2 Conflicts of Interests,” proclaiming such an individual is “more likely...to influence the content of the activity in favor of the [company with whom the interest exists].” The policy then details a complex resolution system to manage conflicts of interest. Although it is clear that Hopkins takes industry bias in its medical education seriously, the “Level 1” and “Level 2” distinctions to minimize multiple conflicts of interest, as compared to a single conflict, are not supported by any evidence and seem counter-intuitive.

Consulting by Johns Hopkins physicians is permitted with certain requirements on disclosure that follow our best practices. In the instance that a physician’s outside employment agreement requires a written contract or goes beyond 26 days in length, a written report detailing the activities and agreements with the company must be sub-

mitted to the dean. Likewise, all consulting arrangements must be disclosed in any related publications or presentations. Hopkins' intent to preserve professionalism in consulting could be further improved by making the disclosures publicly available online.

Hopkins policy also permits faculty to accept "reasonable" honoraria, left undefined. Best-practice guidelines recommend limiting honoraria to market-value payments for contracted scientific and educational activities. It also requires recipients to gain approval prior to acceptance, and to disclose such payments publicly.

In the absence of policy, Hopkins allows its physicians to accept unrestricted educational grants for the purposes of travel.

Hopkins does have a policy that prohibits ghostwriting. Its policy on speakers' bureaus discourages the practice, but it does not explicitly prohibit it. However, the policy may limit the faculty's ability to participate by requiring speakers to be in "full control and authority" over their lecture content. IMAP believes that this leaves too much discretion to individual physicians; they could claim full control and yet repeat company marketing messages. Moreover, the very presence of Hopkins physicians on a speakers' bureau agenda gives legitimacy to this marketing activity. Rather than discourage the practice, IMAP contends that Hopkins should ban it.

3. MedStar Health

As a nonprofit, nonteaching health-care network, MedStar Health is not an AMC. Operating in both Maryland and Washington D.C., it owns eight hospitals—four of which serve Baltimore: Franklin Square Hospital Center, Good Samaritan Hospital, Harbor Hospital, and Union Memorial Hospital. According to its website, MedStar is a \$3.5 billion health-care system that employs

approximately 30,000 people, including affiliated physicians.¹²

Like its university counterparts, MedStar is a tax-exempt 501(c)(3) nonprofit organization. Although it operates as a community-based network of smaller hospitals in comparison to Hopkins' and Maryland's single large facilities, it is overall the largest health-care network in the Baltimore area. It is all the more regrettable, therefore, that it has no conflict-of-interest policies publicly available for review and that it declined to participate in our study.

After sending a package with materials and an initial request for participation, IMAP received confirmation from the office of the senior vice president for audit and compliance that the package had been delivered and we could expect MedStar's participation. Several days later, however, the vice president left a message declining MedStar's participation.

A conversation followed between IMAP and MedStar. MedStar expressed difficulty understanding why IMAP, with funding from The Abell Foundation, was conducting this research. IMAP explained its mission of promoting professionalism in medicine and Abell's interest in conflict-of-interest issues at Baltimore's health-care institutions. However, MedStar was still not inclined to participate, expressing indifference to the policy inquiry of a trusted Baltimore foundation or even the possibility of negative press in the wake of a report's publication. IMAP's president made one additional attempt to secure MedStar's involvement but received no response.

A search of MedStar's website and its annual report uncovered no information about conflict-of-interest policies. A review of MedStar's IRS 990 report did show how the organization responded to the IRS "Self-Dealing Statement." It identifies three of MedStar's directors as having potential conflicts of interest.

These members include a university president whose institution sells undisclosed services to MedStar as part of an affiliation in which MedStar operates the university's hospital; another is a utility company executive whose company sells major utilities to MedStar's hospitals, the third owns stock shares in a company that contracts with MedStar to provide outpatient services. (See Appendix B for the 2006 "Self-Dealing Statement.")

As one of the region's largest networks serving hundreds of thousands of patients a year, MedStar's lack of publicly available conflict-of-interest policies and its decision not to participate with its neighbor institutions in a study aiming to encourage greater accountability and transparency in Baltimore's health-care networks is disappointing. Given the media attention to conflicts of interest, perhaps publicizing this state of affairs will encourage change.

IV. Conclusion

Baltimore's hospital networks exhibit three very different levels of progress in formulating effective policies to govern conflicts of interest. They range from progressive to outdated to ignoring the issue. The University of Maryland has developed a serious response with strong policies. Its policies on gifts, representative access, CME, travel and scholarships, ghostwriting, and speakers' bureaus are especially rigorous. Hopkins should be encouraged to take a cue from Maryland and enact more stringent policies. Although Hopkins' vendor access, CME, and ghostwriting policies are commendable, other policies permit many conflicts of interest to continue and fail to create transparency. At the far end of the spectrum is MedStar Health, which has no publicly available policies.

To encourage change, the glare of

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the media is often helpful. Press coverage can spotlight deficiencies; countless newspaper stories have done just that. Moreover, federal and state legislators are taking a deep interest in conflicts of interest. The efforts of Senators Grassley and Kohl are two notable examples of public officials working to bring the issues of improper industry influence on the nation's physicians and health-care institutions to the forefront.

It is IMAP's hope that its Baltimore report on Maryland, Hopkins, and Med-Star will be shared with many members of the media and with public officials. Change is needed, and this is an especially opportune moment to promote reform.

Endnotes

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- 4 S. 2029: Physician Payments Sunshine Act of 2007, Sponsor: Sen. Charles Grassley (R-IA), Sept. 6, 2007.
- 5 "University of Maryland School of Medicine: Policies Supporting Professionalism and Education in Medicine," University of Maryland School of Medicine, November 2008, 1.
- 6 "University of Maryland School of Medicine: Policies Supporting Professionalism and Education in Medicine," University of Maryland School of Medicine, November 2008, 2.
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- 10 "Johns Hopkins Bayview Medical Center Hospital Administrative Policies," Johns Hopkins University Medicine, November 2006.
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The appendices of this report can be found on the Abell website.

ABELL SALUTES

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ties in Baltimore City, and in Anne Arundel County. The McCullough family was lucky enough to be in and among this in-need population.

Arundel Habitat follows the national Habitat model, supervising volunteer crews to perform the majority of work on each house, including framing, demolition and finish work. The plumbing, heating and ventilation systems and roofing are installed by licensed contractors. Arundel Habitat attempts to finish basements as additional living space when ceiling height allows. New Energy Star-rated appliances, high efficiency heat pumps and replacement windows are installed to maximize energy-efficiency and reduce energy bills.

The McCulloughs appeared for work most every Saturday and some Wednesdays for the nearly six months of work it took to bring the house, a ragged shell when they started to work on it, to the point where it was perhaps the most attractive house inside and out on the block. Mr. McCullough says, "I never knew all the things you could do with a hammer. When we first saw this house--bare walls open to the weather, no second floor, wind blowing through empty windows, and realized that we are really moving in and this house was ours, well, I knew, work and prayer made it happen!" Dan Ellis, Executive Director of Arundel Habitat added, "We are very proud of our volunteers and our families. They work incredibly hard to achieve the dream of homeownership."

Last year the Baltimore City Department of Housing and Community Development, impressed with Arundel Habitat's production of affordable housing, transferred 16 vacant city-owned houses in Brooklyn to Arundel Habitat at nominal prices. In the transac-

tion, user-friendly arithmetic happens: the McCulloughs pay only \$382 a month to Habitat, after paying only \$500 down. A typical bank-financed arrangement, Mr. McCullough says, he discovered after researching, would be more like \$1,100 a month payments, and a \$3,000 to \$5,000 downpayment.

In 2006, The Abell Foundation provided a \$40,000 grant to Arundel Habitat to encourage them to turn their attention to three streets in Brooklyn, just across the Baltimore City line from Anne Arundel County, where they had operated for 18 years. The grant was intended to pay for staff and construction costs for the renovation of three houses to be sold to low income buyers. Since the grant was approved, Arundel Habitat exceeded expectations, raising funding for and completing renovations of a total of 24 vacant houses in Brooklyn, and selling each house to a low income household with no-interest fixed payment mortgages.

Abell Salutes Arundel Habitat For Humanity and its Executive Director, Dan Ellis, and a work-and-prayer formula that puts families like the McCulloughs into beautiful, and beautifully renovated, homes like the McCulloughs', now of Jack Street, in Brooklyn, in Baltimore City, Maryland.

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Appendix A

i Exemplary Conflict-of-Interest Policies at Academic Medical Centers IMAP Analysis – January 2009

Gifts: Yale University, Stanford University

These policies ban all gifts, without exception. Gifts in the form of compensation for listening to a sales pitch or CME event are also forbidden.

Yale University Policy, 2006

“YMG physicians may not accept any form of personal gift from industry or its representatives. (Although the acceptance of a gift of nominal value is unlikely to violate the anti-kickback law, acceptance of most types of gifts of more than nominal value is suspect and may carry serious legal consequences. Accordingly, this provision has been highlighted, and the policy adopted that YMG physicians should not accept any form of personal gift from industry.)”

Stanford University Policy, 2006

“Personal gifts from industry may not be accepted anywhere at the Stanford School of Medicine, Stanford Hospital and Clinics, the Lucile Packard Children’s Hospital, the Menlo Clinic or off site clinical facilities such as other hospitals at which Stanford faculty practice, outreach clinics and the like.

“Individuals may not accept gifts or compensation for listening to a sales talk by an industry representative.

“Individuals may not accept gifts or compensation for prescribing or changing a patient’s prescription.

“Individuals must consciously and actively divorce clinical care decisions from any perceived or actual benefits expected from any company. It is unacceptable for patient care decisions to be influenced by the possibility of personal financial gain.

“Individuals may not accept compensation, including the defraying of costs, for simply attending a CME or other activity or conference (that is, if the individual is not speaking or otherwise actively participating or presenting at the event).”

Meals: University of Michigan, Stanford University

These policies eliminate meals of any size or value.

University of Michigan Policy, 2005

“Food or drink may not be provided directly by vendors.”

Stanford University Policy, 2006

“Meals or other types of food directly funded by industry may not be provided at Stanford School of Medicine, Stanford Hospital and Clinics, the Lucile Packard Children’s Hospital, or the Menlo Clinic.”

“Q. Why preclude meals? Do they really affect patient care decisions?”

Research has shown that even di mimimus gifts, such as pens, engender a sense of obligation on the part of the recipient. Moreover, research has shown that in cases where a doctor has a pen or pad advertising a particular product, that product gets prescribed more often (AMA Guidelines Regarding Industry Interactions; “Drug Makers Pay for Lunch as They Pitch,” New York Times, July 28, 2006). Thus it has been shown that such gifts, including meals provided by Pharma, can influence the decision-making process. Our goal is to provide our patients with the best, most objective care. This is why we have chosen to eliminate such incentives.

Q. Can a sales rep take a doctor out to lunch or dinner for a business purpose?

A. While our policy does not explicitly prohibit restaurant meals with industry reps, we strongly discourage them because of the implied quid pro quo that is present in such situations. We suggest, instead, that industry reps be invited to meet with Stanford faculty or medical staff in accordance with the site access provisions of this policy, which are described in the next section of these FAQs.”

Pharmaceutical Representative Access to Physicians: University of Pennsylvania

The policy forbids pharmaceutical representatives from patient areas. University of Pennsylvania is the most detailed, and it covers many interactions.

University of Pennsylvania Policy, 2006

Registration:

“Pharmaceutical company representatives, on their first visit to HUP/CPUP will be directed to the Department of Pharmacy Services, where they will be provided with a copy of this policy. The representative will sign a statement to the effect that he/she has received and understands the policy. The representative will then be directed to the HUP Security Department to obtain the appropriate identification badge. The representative must wear this identification badge at all times during all HUP/CPUP campus visits.

“Pharmaceutical company representatives must provide the following information to the Department of Pharmacy Services secretary: 1) current business card; 2) immediate supervisor’s name, work phone, and address. Any changes to this information must be promptly forwarded to the Department of Pharmacy Services.”

Scheduling:

“Pharmaceutical company representatives are required to have a scheduled appointment whenever they visit the Hospital or CPUP. Representatives who arrive in the Hospital or CPUP location without an appointment should be asked to leave the facility and subsequently reported to the Director of Pharmacy Services. Exceptions include visits to expedite removal of recalled or return products in coordination with Pharmacy Services Department or to deliver new products information to the Pharmacy Services Department.

“Pharmaceutical company representatives visiting HUP/CPUP for any business reason will report to the secretary in the Department of Pharmacy Services. Representatives also are required to register with the department in which they have a scheduled appointment.

“HUP/CPUP reserves the right to limit the number of pharmaceutical representatives a single company has visiting HUP/CPUP at any given time.”

Restricted Areas:

“Pharmaceutical company representatives are not permitted to detail professional staff in any patient care unit, including inpatient units, nursing stations, conference rooms, physician lounges, outpatient clinics (patient areas), preoperative and operative areas and the Emergency Department. Representatives must only conduct meetings in private offices.”

Samples: University of Michigan, University of Wisconsin – Madison

These policies remove samples from the doctor/pharmaceutical representative relationship, and ensure proper storage, labeling, and dispensing of samples. Rather than physical samples, vouchers are provided when necessary.

University of Michigan Policy, 2004

“Sample Medications are not permitted in UMHHC facilities except as noted below. This includes both patient care and non-patient areas.

“Vouchers approved by the University of Michigan Health System’s Ambulatory Formulary Committee may be distributed by UMHHC ambulatory care sites in order for patients to receive complimentary starter medications from a pharmacy of their choice. The Ambulatory Formulary Committee will determine a formulary of UMHS-preferred medications, which then may be available through vouchers. Only vouchers approved [by] the Ambulatory Formulary Committee are permitted to be used by UM clinicians at UMHHC.

“Non-approved vouchers may not be distributed by PSRs to UMHHC ambulatory care sites, nor dispensed by UMHHC personnel at UMHHC sites.

“Under special circumstances in which there is a legitimate clinical need, with the approval noted below, sample medications may be permitted in UMHHC. Specific requests to have physical samples in UMHHC clinic must be made on the Special Cause Sample Request Form, and be approved by the Ambulatory Formulary Committee and the Site Medical Director.”

University of Wisconsin Policy, 2006

“Samples are defined as a supply of prescription medication provided by a manufacturer to prescribers for the purpose of encouraging the prescriber to select the sampled medication for ongoing use by the patient. Dispensing of samples of prescription medications from a prescriber’s office must comply with all labeling,

storage, and handling procedures required by the Wisconsin Pharmacy and Medical Examining Boards and the Joint Commission on Accreditation of Healthcare Organizations.

Samples (except as noted in section III.A.2) may not be used or stored in any facility of UWHC required to comply with JCAHO standards.

Samples are specifically prohibited in inpatient facilities per JCAHO standards. Samples found on any inpatient unit including those found in patient rooms will be removed and destroyed.

Prescribers are discouraged from accepting samples for personal use or from storing them in their offices.

Samples acquired for personal use by prescribers may not be used to treat UWHC patients.

Exceptions - In some specific situations, samples may be needed to provide trial supplies of medication that cannot reasonably be provided through the use of the Drug Voucher System (see section III.B). These products are designated "exempt samples."

Formularies: Veterans' Affairs and Yale University

Veterans' Affairs (VA) and Yale University each present pieces of an appropriate policy. As Yale's states, formulary committees, and all individuals involved in institutionwide purchasing decisions, should be completely conflict-free. Also, as the VA policy states, pharmaceutical representatives should be forbidden from promoting non-formulary drugs.

Yale University Policy, 2006

"YMG physicians who are involved in institutional decisions concerning the purchase of or approval of medications or equipment, or the negotiation of other contractual relationships with industry, must not have any financial interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensated relationship) in pharmaceutical companies that might benefit from the institutional decision. This provision is not intended to preclude the indirect ownership, through mutual funds or other investment vehicles, of equities in publicly traded pharmaceutical companies by Yale faculty."

VA Policy, various

"In-service training, continuing education presentations and promotional materials that primarily focus on non-formulary drugs/supplies are prohibited. Exceptions may be granted by the VISN committee responsible for such oversight."

Continuing Medical Education: University of Wisconsin-Madison and University of Massachusetts-Worcester

Although the ACCME has minimum standards, an adequately stringent policy would have all CME funding channeled through a central pool from which CME grants were allocated internally. The University of Wisconsin's policy does not create such a pool, but it has established a strong peer-review process to ensure that material produced for CME is scientifically sound. CME material created by physicians identified as having high levels of conflict is reviewed by a peer physician without conflicts in the area. This policy would be strongest if it followed the guidelines suggested in the JAMA piece stating that all industry donations should be funneled through a central repository rather than given to individuals and departments.

At the University of Massachusetts, donations for CME are funneled into the UMass Memorial Foundation; they can be restricted by the donor for use in a particular clinical department, but not to a specific division, person or program.

University of Wisconsin Policy, 2006

"Staff, planners, instructors, and/or managers that have financial relationships with commercial interests may produce educational materials that are influenced by these relationships, thus resulting in a conflict of interest. When this occurs, the OCPD will implement "tertiary prevention" measures to resolve all COI prior to any continuing medical education activity sponsored by the University of Wisconsin School of Medicine and Public Health. Active measures for resolving conflict of interest in CME include, but are not limited to, the following measures:

Careful review of educational content, coupled with the authority for peer review to alter content of any educational material that has commercial bias
Alter or limit the role(s) of the individual so that the financial relationship is no longer relevant

Exclude an individual from participating in content creation or delivery
Deny CME certification to select portions of an educational activity
Ensure that CME content reflects the best available evidence"

Faculty members are stratified according to conflict-of-interest risk. All faculty members, regardless of risk, receive faculty letters delineating Office of Continuing Professional Development policy, and their CME is screened by asking participants if they detected commercial bias. Faculty members with highest risk and very high risk are also subject to a peer review of their content.

University of Massachusetts Policy, 2007

"All CME and GME events hosted or sponsored by UMMMC or UMMMG must comply with the requirements below and the ACCME Standards for Commercial Support whether or not CME credit is awarded:

UMass Memorial Foundation. All funding from Clinical Vendors to support CME and GME programs must be directed to the UMass Memorial Foundation. Funding may be restricted to a clinical department and must be overseen by the Department Chair. Funding may not be restricted to a clinical division, a specific program or an individual. An oversight committee comprised of physician and other leaders will oversee Clinical Vendo sponsorship exceeding establishing thresholds (see below) to ensure potential conflicts of interest.

UMass Memorial and UMass Medical School Sponsored Meetings: International, national, and regional Meetings co-sponsored by UMass Memorial or UMass Medical School: these meetings are designed to benefit the broader community of physicians. Industry funding to support such meetings is acceptable provided such funding is exclusively for support of such meetings and, not to directly benefit UMass Memorial or UMass Medical School.

Clinical Vendors are not permitted to bring food into any UMass Memorial facility or to any meeting sponsored by UMass Memorial on or off campus and are prohibited from paying for such food.

An oversight committee of rotating UMass Memorial and UMass Medical School physician leaders will function in an advisory capacity regarding the implementation and oversight of this policy and will review and oversee industry sponsorship exceeding established thresholds to assess potential conflicts of interest and to propose approaches for management of conflicts of interest. The oversight committee will review any vendor contribution exceeding \$10,000 in support of CME, GME, or general research support in any one fiscal year. The committee shall also have the following responsibilities:

Assess potential conflicts of interest associated with other financial relationships involving the sponsoring vendor and targeted department or division, such as CME/GME support, clinical research funding, and vendor purchases;

Review uses of funds for consistency with restrictions and policy;

Review aggregate vendor contributions semiannually."

Honoraria and Consulting: University of Washington (Washington State Policy)

The best policies require the compensation to be of fair market value, with a clear set of deliverables outlined. Disclosure and prior approval of the agreement is also required for consulting honoraria.

Washington State Policy, last update 2007 (applies to University of Washington employees)

(For the complete policy, see <http://apps.leg.wa.gov/RCW/default.aspx>.)
"RCW 42.52.130

Honoraria

(1) No state officer or state employee may receive honoraria unless specifically authorized by the agency where they serve as state officer or state employee.

(2) An agency may not permit honoraria under the following circumstances:

(a) The person offering the honorarium is seeking or is reasonably expected to seek contractual relations with or a grant from the employer of the state officer or state employee, and the officer or employee is in a position to participate in the terms or the award of the contract or grant;

(b) The person offering the honorarium is regulated by the employer of the state officer or state employee and the officer or employee is in a position to participate in the regulation; or

(c) The person offering the honorarium (i) is seeking or opposing or is reasonably likely to seek or oppose enactment of legislation or adoption of administrative rules or actions, or policy changes by the state officer's or state employee's agency; and (ii) the officer or employee may participate in the enactment or adoption."

"RCW 42.52.120

Compensation for outside activities

No state officer or state employee may receive any thing of economic value under any contract or grant outside of his or her official duties. The prohibition in this subsection does not apply where the state officer or state employee has complied with *RCW 42.52.030(2) or each of the following conditions are met:

the contract or grant is bona fide and actually performed;

the performance or administration of the contract or grant is not within the course of the officer's or employee's official duties, or is not under the officer's or employee's official supervision;

the contract or grant is neither performed for nor compensated by any person from whom such officer or employee would be prohibited by RCW 42.52.150(4) from receiving a gift."

Travel Funds, Fellowships, Scholarships: University of Massachusetts - Worcester

The University of Massachusetts-Worcester is in the process of implementing a policy that effectively channels scholarship money through a centralized location to avoid bias. Industry money is given to the UMM Foundation, not to individuals or departments.

University of Massachusetts Policy, 2008

"Clinical Vendor support for scholarships and fellowships must comply with UMMMC and UMMMG policy requirements for such funds, including the execution of an approved budget and written gift agreement through the UMass Memorial Foundation, and maintenance of the funds in an appropriate restricted account, overseen by the department chair. Selection of recipients of scholarships or fellowships must be within the sole discretion of the department chair or, in the case of graduate medical education, the associate dean for graduate medical education."

"Clinical Vendor support for other trainee activities, including travel expenses or attendance fees at conferences, must be accompanied by a written gift agreement through the UMass Memorial Foundation, maintained in an appropriate account overseen by the respective department chair."

Speakers' Bureaus, Ghostwriting: University of Pittsburgh

The best policies will completely and clearly prohibit both ghostwriting and speakers' bureaus. The clearest policy is currently the University of Pittsburgh Medical Center policy.

University of Pittsburgh Policy, 2007, (effective 2008)

"While one of the most common ways for the SOHS and UPMC to disseminate new knowledge is through lectures, 'speakers['] bureaus' sponsored by Industry may serve as little more than an extension of the marketing department of the companies that support the programming. Before committing to being a speaker at an Industry-sponsored event, careful consideration should be given to determine whether the event meets the criteria set forth in Section 6 of this policy, relating to Industry Sponsored Meetings. SOHS or UPMC personnel may not participate in, or receive compensation for, talks given through a speakers['] bureau

or similar frequent speaker arrangements if: (a) the events do not meet the criteria of Section 6; or (b) the content of the lectures given is provided by Industry or is subject to any form of prior approval by either representatives of Industry or event planners contracted by Industry; or (c) the content of the presentation is not based on the best available scientific evidence; or (d) the company selects the individuals who may attend or provides any honorarium or gifts to the attendees.

Under no circumstances may SOHS and/or UPMC personnel be listed as co-authors on papers ghostwritten by Industry representatives. In addition, SOHS and/or UPMC personnel should always be responsible for the content of any papers or talks that they give, including the content of slides."

Appendix B

ii MedStar Health, Inc. TY 2006 Self-Dealing Statement

"John J. DeGioia, Ph.D.: Dr. DeGioia is president and CEO of Georgetown University. Georgetown University and MedStar Health, Inc. have maintained a clinical partnership agreement whereby MedStar Health owns and operates Georgetown University Hospital's clinical enterprise, which purchases various services stemming from Georgetown University as part of this affiliation.

"John P. McDaniel: Mr. McDaniel has ownership shares in CHS, which has contracted with MedStar Health Outpatient Physician Services.

"William R. Roberts: Mr. Roberts is president of Verizon Maryland, Inc., which provides telecommunications services to customers in Maryland, including MedStar Health, Inc."