REPORT ON PHYSICIAN COMPENSATION ARRANGEMENTS

INTRODUCTION

This Report on Physician Compensation concerns the pervasive and largely unregulated conflicts of interest that arise from the financial relationships between physicians and pharmaceutical and medical device companies. Such financial relationships threaten to bias medical decision-making and compromise patient health. The residents of the State of New Jersey deserve a medical community that is free from such conflicts.

In 2007, the Division of Consumer Affairs was tasked with identifying ways in which the potential for conflicts of interest between doctors and pharmaceutical companies and medical device manufacturers could be minimized to ensure that patient care is always guided by the unbiased, best judgments of the treating doctor. As part of that initiative, the Division has engaged in a dialogue with physicians, pharmacists, hospital executives, and pharmaceutical industry and insurance company representatives, who provided insight on current developments in industry, academia, the medical community and state and federal initiatives. Through that dialogue, as well as the substantial, independent research undertaken, the Division of Consumer Affairs devised the policy recommendations contained in this report presented to the Attorney General. The report recognizes that there are beneficial interactions between physicians and pharmaceutical and medical device companies, but urges the adoption of regulations that will: (a) limit such interactions to those that advance the public health; and (b) regulate such interactions in order to prevent abuse.

The issuance of this report is timely in light of the ongoing national debate—from academic medical journals to the halls of Congress—on physician compensation.[1] This debate has already led to significant changes to industry's voluntary codes of conduct and has encouraged leading companies, health care institutions and academic medical centers to voluntarily adopt reforms, such as curtailing gift-giving and mandating disclosure of other financial interests.[2] Yet, these efforts have only begun to reshape the relationship between industry and physicians and to bring about needed reform. Indeed, as recently as April 2009, the Institute of Medicine, part of the National Academy of Sciences, issued a report that criticized prevalent industry practices pertaining to its financial entanglements with physicians and called upon medical professionals to avoid such financial arrangements.[3]

The function of this report to the Attorney General is to recommend a reform initiative that will complement and advance these ongoing national efforts. As the head of the Department of Law and Public Safety, the Attorney General, together with the Board of Medical Examiners (the "BME") and the Division of Consumer Affairs, regulates New Jersey's 33,000 physicians. The reforms proposed herein would create enforceable standards applicable to New Jersey's physicians to regulate their financial relationships with industry. While several states have imposed disclosure obligations and

other limitations on industry,[4] no state has imposed such requirements on physicians. The imposition of such obligations on physicians is a critical element of the initiative to impose principled standards on the relationships between doctors and industry. These standards will benefit New Jersey's patients and health care consumers.

This report outlines recent developments in the study of physician conflicts of interest, identifies reform models adopted in industry voluntary codes of conduct and standards adopted in other jurisdictions, and makes specific regulatory and legislative recommendations. Part I addresses gifts, reimbursements and financial arrangements between physicians and industry. Part II concerns the disclosure of such financial arrangements. Part III proposes measures to limit the influence of industry on continuing medical education. Part IV recommends reforms to control the influence of industry on physician prescribing practices through the use of data mining. Part V makes specific recommendations for limiting conflicts of interests in the context of medical academia. Part VI addresses physician accountability for research and promotional activities. Part VII addresses health care facilities. Part VIII addresses academic detailing.

I. GIFTS, FOOD AND REIMBURSEMENTS

For years, pharmaceutical companies and medical device manufacturers have given physicians expensive gifts, free vacations, and lavish meals.[5] In addition, recent studies demonstrate that even gifts of nominal value, including food, have an impact on physician prescribing practices.[6] The receipt of gifts, payments and perks - large and small – engenders a loyalty (or feeling of obligation) in the receiver to reciprocate.[7] This loyalty, either consciously or unconsciously, could influence subsequent medical decision-making. Indeed, even physicians recognize that industry payments and gifts can compromise medical judgment. Studies show that doctors agree that payments and gifts influence the behavior of their colleagues, but believe that they themselves are not personally influenced by accepting such payments and gifts.[8] The purpose of this section is to propose reforms that will eliminate the influence of such gifts on physicians.

Industry also recognizes that gifts are improper and can create influences that do not serve patients' interests. Two leading industry associations have adopted voluntary codes of conduct designed, among other things, to limit such gifts. Pharmaceutical Research and Manufacturers of America ("PhRMA"), representing 30 pharmaceutical and biotechnology research companies,[9] has developed a detailed ethical code to guide its members.[10] The Advanced Medical Technology Association ("AdvaMed"), representing the medical device and equipment manufacturers, has also adopted a voluntary code of ethics.[11] The PhRMA and AdvaMed Codes (the "Codes") prohibit member companies from, among other things, providing entertainment,[12] vacations or meals to physicians, unless the meals are modest and are offered in connection with an informational presentation at a medical office or in a clinical setting.[13] They also have prohibited member companies from distributing non-educational branded items, such as pens and mugs.[14] Parts A through C below, which, in turn, address gifts, food and free samples, contain recommendations for regulatory reform that mirror and, in certain instances, go

beyond the substantive provisions of the PhRMA and AdvaMed Codes, while still permitting those gifts, including free samples, that benefit patients.

A. Gifts

While the Codes provide a valuable blueprint for reform, standing alone they cannot eradicate conflicts of interest because they do not provide a mechanism for enforcement; nor do they apply to all companies and manufacturers. Accordingly, in light of the unenforceability of these voluntary codes, several states have created mandatory standards through legislation that require pharmaceutical companies to annually and publicly report gifts to physicians and hospitals or standards that otherwise prohibit or limit such gifts. The legislative approaches range from requiring a declaration of compliance with industry codes (California), to prohibiting companies from giving gifts over a certain threshold (Minnesota), to the licensure of sales representatives (the District of Columbia).[15] And, as will be discussed in greater detail in Part II below, proposed federal legislation on health care reform in both the U.S. Senate and the House of Representatives includes demands for transparency, requiring manufacturers to publicly disclose gifts and other payments to physicians in a national database.[16]

To ensure unbiased medical decision-making that benefits patients, it is incumbent upon New Jersey to likewise create its own enforceable standards with a true mechanism for compliance. These standards will limit the receipt of gifts to those that directly benefit patients and to those that indirectly benefit patients by advancing physician learning or legitimate research goals.

Recommendation 1

Amend BME regulations to expressly forbid a licensee from accepting from any pharmaceutical or medical device manufacturer any of the following, either directly or indirectly:

- Any payment or other subsidy (including tuition, fees, travel, lodging or other incidental expenses) to support attendance as a participant at an accredited continuing medical education program.

- Any fees or travel or lodging reimbursement for non-faculty or non-consultant attendees at company-sponsored meetings.

- Items intended for the personal benefit of a licensee (including, but not limited to, floral arrangements, artwork, CDs, DVDs or tickets to a sporting event) or items that may have utility in both the professional and non-professional setting (including, but not limited to, a DVD or a CD player).

- Any payment in cash or a cash equivalent (such as a gift certificate) unless it is compensation for bona fide services (such as

serving as a consultant or participating in research or publication activities).

- Any company-funded entertainment or recreational item, unless the health care professional is a salaried employee of the manufacturer.

The regulations, however, should permit the receipt of items that provide a direct benefit to patients, such as, samples or anatomical models for use in examination rooms. In addition, the regulations should permit physicians to accept things of value, such as, remuneration for service as a speaker or faculty organizer for CME events, which indirectly benefit patients by advancing physician learning or legitimate research goals.

B. Food

The practice of providing free food to practitioners and their staffs raises concerns as to whether unbiased medical decision-making is occurring. Providing free food to physicians and staff in an office setting or at an educational/promotional dinner has no benefit to patients or to the broader public, and would appear to have no other purpose than to gain access and favor with the physician. The Codes recognize the potential for undue influence, but still allow companies to provide "modest meals" in a clinical setting if the meals accompany an informational presentation.[17] The perception exists, however, that industry continues to provide food to physician practices and hospitals as a means to influence medical decision-making. As Daniel J. Carlat, MD, assistant clinical professor of psychiatry at Tufts University of Medicine and a former paid speaker for the pharmaceutical industry stated:

> Pens, post-it notes and mugs have never been the focus of critics of industry marketing tactics . . . [t]hat is chump change compared to the platters of food brought in to feed the entire office staff, which is done to cement a good relationship with the doctor and to ensure continuous access in order to deliver sales pitches.[18]

Physicians interested in learning about new products can accept literature about new treatments and therapies and listen to informational company presentations in a clinical setting, but they should be required to pay the fair market value for any food provided. Moreover, it would be appropriate for physicians to accept modest meals in an educational setting to maximize the time at an accredited seminar that can be devoted to physician learning. The BME regulations, however, should be amended to ensure that food does not improperly influence medical decision making.

Recommendation 2

Amend BME regulations to prohibit physicians and physician in-office staff from accepting food from manufacturers, whether in-office, at health care facilities or in commercial venues, such as restaurants.

Recommendation 3

Amend BME regulations to require physicians attending unaccredited educational or promotional sessions organized by manufacturers at which meals are served, to pay the fair market value for the meals served in connection with those sessions.

Recommendation 4

Amend BME regulations to allow the receipt of modest meals at CME seminars, third-party conferences and professional meetings accredited by the Accreditation Council for Continuing Medical Education or the American Asteopathic Association, where the provision of meals facilitates the scheduling of the educational program to maximize physician learning, and where such meals are provided at the discretion of the CME provider. Such meals may not be paid for directly by manufacturers.

C. Free Samples

The retail value of drug samples distributed in the United States was more than $18 billion in 2005.[19] The provision of samples for newer, more expensive brand-name medications is a key component to pharmaceutical company marketing.[20] The availability of samples affects physician prescribing, and may lead to the increased prescription of those marketed drugs.[21] The use of samples results in increased costs for patients and third party payors, including government programs, because once patients initiate a course of treatment with sample medications, the likelihood of their continuing on the same, more expensive medication long term is increased.[22]

Notwithstanding these concerns, there is a consensus among physicians that the provision of sample medications benefits patients and should be continued. A 2003 poll reported that close to 90% of physicians surveyed found product samples "valuable" or "extremely valuable" in their practices.[23] According to the chairman of the Asthma and Allergy Foundation's Medical-Scientific Council, samples are an important tool to discover which medications work for patients.[24] Furthermore, a recent Kaiser Family Foundation survey found that 75% of physicians frequently (58%), or sometimes (17%), give patients free samples to assist them with their out-of-pocket costs.[25] Another survey established that a "patient's financial situation" was a consideration or strong influence 86% of the time that physicians dispensed a free sample.[26] A patient's insurance status was a consideration or strong influence 58% of the time.[27] According to Robert M. Sade, MD, samples provide "a clear and direct benefit to patients who have a medically indicated need for treatment, but lack the resources to obtain the necessary care."[28]

Moreover, providing samples is perceived by patients to be both a convenience and a cost savings. Virtually every jurisdiction that has adopted a disclosure requirement has excluded the value of samples. Vermont, Minnesota, Maine, and most recently Massachusetts, all expressly exempt samples from the ban on gifts and do not require that their value be included when calculating threshold amounts.[29] The District of Columbia is, at present, the only jurisdiction that includes the value of samples in the accounting of the reportable things of value, if the samples are not distributed to patients free of charge.[30] Significantly, the physician payment disclosure provisions in the current health care reform bills in both the Senate and the House of Representatives also exempt samples.[31]

Recommendation 5

Amend BME regulations to permit continued receipt of sample medications by physicians for the exclusive benefit of patients without charge. The value of samples would not count towards the disclosure threshold.

II. DISCLOSURE

While physicians should not be permitted to accept gifts from industry, physicians do enter into other types of permissible financial arrangements with pharmaceutical or device companies that should be known to patients. Such arrangements include serving as consultants, participating in the development of new treatments and therapies, and providing training on behalf of the companies, all of which are necessary activities. Such financial arrangements may play a role in influencing physician behavior and can create excessive or inappropriate loyalties and entanglements.[32] Greater transparency of these arrangements will serve to deter the most flagrant abuses. Indeed, a number of states have addressed this issue through legislation requiring companies to annually and publicly report payments they make to physicians and hospitals.[33] Even PhRMA and AdvaMed have publicly expressed their support for the disclosure of appropriate transfers of value through a national database.[34]

At the same time, industry representatives expressed concern that physicians will be deterred from attending pharmaceutical or medical technology-sponsored CME or participating in clinical trials and research that lead to product innovation and advances in life-saving technology because of the administrative burdens they would encounter if disclosure of payments is required. Moreover, representatives from PhRMA and AdvaMed argue that any additional administrative burdens could reduce clinical research and dissuade academicians from seeking research opportunities in New Jersey. Notably, federal regulations already require the collection and reporting of much of this information, though such regulations are poorly enforced.[35]

On balance, these objections are speculative and have not been seen in the clinical research context in other jurisdictions that have enacted legislation on this topic. Moreover, a national database does not yet exist. Therefore, New Jersey should implement appropriate disclosure mechanisms to provide patients with tools now

available in other states. Models in development on the federal level and those adopted in other jurisdictions provide a good framework with which physician regulations can dovetail.

On the federal level, the Senate Finance Committee recently released its policy options for heath care reform, which included the Physician Payment Sunshine Act ("Sunshine Act"). The proposed Sunshine Act contains several requirements. First, manufacturers of covered drugs, devices, biological and medical supplies that make a payment or transfer of value to a physician must disclose certain information in electronic form on an annual basis to the Secretary of Health and Human Services. The disclosure would include information on the recipient, and information on the payment, including value, form and nature, and if the payment is related to marketing, education or research. In addition, if the recipient transfers payment to another, the manufacturer must disclose that information. Delayed reporting requirements would apply for payments made pursuant to a product development agreement or clinical trial.

There are exclusions to the proposed federal disclosure requirements, including: payments or transfers of ten dollars or less, unless the aggregate annual payments or transfers to a recipient exceeds $100, in which case all payments or transfers must be reported; samples intended for patient use; patient education materials; a covered device loaned for a short period of time; discounts and rebates; payments made to a physician for the provision of health care to employees; payments to a physician who is also a licensed, non-medical professional if the payment is solely related to non-medical services; payments to a physician solely for services related to a civil or criminal action or an administrative proceeding; and in-kind items used for charity care.

Also, the manufacturer or related group purchasing organization is required to report information regarding ownership or investment interest, other than publicly traded securities and mutual funds, held by a physician or immediate family member in the manufacturer or group purchasing organization during the preceding year.

Civil monetary penalties of $1,000 to $10,000 would be imposed for each payment or transfer not reported to a maximum of $150,000. Knowing violations would be subject to a civil monetary penalty of $10,000 to $100,000 for each payment or transfer not reported, not to exceed $1,000,000 annually.

The Physician Payments Sunshine provision of the current House of Representatives' health care reform bill includes many of the same requirements, but the House bill exempts the reporting of individual payments and gifts valued at less than five dollars. The House bill, however, requires manufacturers to make annual aggregate payment reports, which would include the total value of transfers of value below this five dollar threshold.[36]

On the state level, several states and the District of Columbia have already enacted their own "sunshine laws" that set limits on industry payments to physicians and/or require disclosure of the payments. Although the limitations on payments in these jurisdictions vary, each jurisdiction has required industry to disclose payments

to physicians in excess of an established dollar amount, ranging from $25 to $100. [37] The experiences in other jurisdictions highlight the need to ensure public access to this information.

Recommendation 6

Mandate, as part of the BME biennial renewal process (until the creation of an on-line system allowing regular updates), that physicians disclose whether they accepted more than $200 during the preceding two years from manufacturers in the form of compensation, food, travel, consulting fees or honoraria, funding for research, funding for education, stock or stock options, ownership or investment interest, or any other economic benefit. The required disclosure should include the name of the company, the value, date and nature of the payment, and if applicable, the name of the product, and whether the payment is related to marketing, education or research pertaining to a specific drug, device, biological or medical supply.

Recommendation 7

Create a searchable, user-friendly database to make physician-disclosed information available to the public and require physicians to post a notice in their offices advising consumers of the existence of the database. If technologically feasible, doctors should be responsible for updating disclosures into the database periodically. And as an alternative means of reporting, companies should be given access to provide direct disclosure of information to the database.

Recommendation 8

The State of New Jersey should enact legislation requiring manufacturers to disclose payments and other things of value made to physicians, physician practices and physician groups - identifying the name, nature and purpose for the payment, unless the payment has been reported to a recognized national database.

III. CONTINUING MEDICAL EDUCATION

Physicians are required to participate in continuing medical education ("CME") as a condition of licensure renewal.[38] The FDA requires that industry limit its CME involvement to financial support, otherwise it might cross the line into advertising or product labeling, both of which are subject to agency oversight. Specifically, CME courses are to be "nonpromotional and otherwise independent from the substantive influence of the supporting company," with CME providers maintaining full control over program planning, including the selection of speakers and development of course content.[39]

Even though CME providers maintain control of program planning, many observers believe that industry-funded courses are nonetheless promotional in nature, focusing on the newest available treatments and off-label uses that lack evidence of

safety or efficacy.[40] Industry funding for accredited CME was approximately $1 billion in 2008.[41] As a Senate Finance Committee report put it, "it seems unlikely that this sophisticated industry would spend such large sums on an enterprise but for the expectation that the expenditures will be recouped by increased sales."[42]

Many drug and device companies dispense funds via requests for proposals in which they specify the diseases or conditions to be covered by funded activities.[43] Even in the absence of an explicit agreement, the sponsoring company likely expects that the funded activity will include a discussion of the sponsor's product or products which treat the specified disease or condition. And the provider knows that it is unlikely to receive funding in the future if such a discussion is not included.[44] To give another example of permissible influence, the physicians who serve as CME faculty for courses addressing a particular disease or condition often serve as company-paid promotional speakers on the same disease or condition. This, too, undermines confidence in the independence of CME presentations.

While empirical evidence of pro-industry bias in industry-funded CME is limited, the authors of a literature review commissioned by the Accreditation Council for Continuing Medical Education ("ACCME"), the primary accrediting body for the United States and Canada, concluded that the few extant empirical studies do establish that CME affects attendees' prescribing patterns.[45]

To address these concerns, all CME courses should meet ACCME or American Osteopathic Association ("AOA") standards for creating a separation between educational content and the source of the subsidy. In addition, efforts to encourage a phase in for CME courses of evidence-based educational opportunities should be launched.

Recommendation 9

Amend BME regulations to provide credit only for those CME courses that meet ACCME or AOA standards that specifically bar the CME provider from obtaining advice from a subsidizing company as to faculty or content. Promotional dinners and workshops would not be counted towards CME mandates.

Recommendation 10

Amend BME regulations to impose an obligation on physicians who are engaged as CME speakers to directly disclose to physician-learners, at the beginning of the presentation, the receipt of reportable compensation from manufacturers.

Recommendation 11

Amend BME regulations to direct that 25% of the required CME be obtained in evidence-based educational programs or through academic detailing. (See Part VIII,

Academic Detailing, below). This requirement would be phased-in over future biennial renewal periods.

IV. DATA MINING

Healthcare Information Organizations (HIOs), companies that acquire, compile and analyze prescription data and other medical information for resale, have been aggregating and marketing prescribing data since 1993.[46] HIOs are able to manipulate data into highly marketable information by purchasing prescription data from pharmacies.[47] This data, while encrypting patient identifying information, contains a physician identifier number that is then combined with the AMA Physician Masterfile Database,[48] allowing identification and other information about the prescriber to be paired with each prescription. Industry then purchases this information to tailor marketing to each physician's prescribing habits.[49]

This information is extremely valuable to the pharmaceutical industry. Marketing departments and field sales representatives use the data to refine and improve the effectiveness of their evolving promotional strategies.[50] Distribution of drug samples can be targeted based upon a physician's volume of patients for new start or maintenance medications and for historical prescribing practices. Physicians in a sales territory can be prioritized, based upon volume of products used, in the event of adverse news concerning products. Companies can use the data to influence physicians by hiring them to give promotional speeches as a reward for high volume prescribing of their products.[51] A physician promoter of one drug recalled:

> Before each of these Lunch 'n Learns, as they are called, the rep would fax me a little cheat sheet about the doctor we'd be visiting. This sheet spelled out exactly how many prescriptions for which anti-depressants this doctor was writing. Doctors who wrote too much Celexa and Zoloft, and not enough Effexor, were crucial targets, and I was implicitly encouraged to give these misguided doctors a particularly hard sell.[52]

Physician reaction to the use of this data has been largely negative. A survey conducted by the Kaiser Family Foundation found that once aware of the sale of their information, 43% of the physicians were bothered by the practice, but understood why it was done, and 31% were strongly opposed to the practice.[53] An AMA survey found a 66% disapproval rate - prompting the need for a response from the AMA.[54] In 2004, the American College of Physicians and several other national and state medical societies formally asked the AMA to cease activities that allow the release or sale of physician-identified prescribing information.[55] In response, the AMA and HIOs developed an "opt out" mechanism for physicians listed in the AMA Masterfile.[56] On July 1, 2006, the

AMA launched its opt-out program, as an alternative to more restrictive measures being called for at the time.[57] Critics of the program noted that little effort has been made by the AMA to aggressively publicize the program.[58] Many physicians remain unaware of its existence.[59]

At the same time, states have adopted legislative restrictions on the sharing of prescriber identified data.[60] Though early legislative efforts were challenged in court, recent decisions have affirmed the states ability to regulate the practice. [61] Recently, in IMS Health v. Ayotte, 550 F.3d 42 (1st Cir. 2008), *cert. denied,* 129 S. Ct. 2864 (2009), the First Circuit upheld the constitutionality of New Hampshire's Prescription Information Law, which prohibits the transfer of physicians' prescribing histories for use in detailing, although permitting it for other commercial purposes. In contrast to the District Court, which had found the law to be an unconstitutional restriction on free speech, the First Circuit determined that the law regulated the conduct of data mining – the aggregation, compilation and transfer of data for detailing – not the free speech rights of any of the parties. Citing the potential for influencing physician prescribing practices and the increased expense of the drugs promoted by detailers, the Court determined that New Hampshire's law appropriately regulated the conduct which had the potential to cause the greatest harm while regulating only the type of speech that influences a party's bargaining power in negotiations, not the type of speech afforded the highest level of protection under the First Amendment.[62] In light of this development, New Jersey legislators should develop a legislative proposal to address data-mining concerns.

Recent amendments to the PhRMA Code also have sought to address concerns about these practices by restricting access to this data. The Code requires member companies that choose to utilize prescriber data to develop policies to safeguard the confidentiality of such information and to protect against its misuse, and to abide by the wishes of any health care professional who asks that his or her prescriber data not be made available to company sales representatives.[63]

Recommendation 12

Utilize the BME biennial renewal process and the BME website to acquaint physicians with the AMA's opt-out of data-mining program.

Recommendation 13

Amend Board of Pharmacy regulations to require pharmacies to maintain documentation confirming that prescribers have consented to the sale of their prescribing information.

Recommendation 14

The State of New Jersey should enact legislation to restrict the transfer, use or sale of prescriber-identifiable prescription information for commercial purposes.

V. PHYSICIANS-IN-TRAINING

Industry funding for medical education and the operation of academic medical centers also has significantly increased.[64] Financial relationships among industry and academic medical institutions, departments, and faculty are common and exist, according to one study, in at least 80% of clinical departments.[65] Restricted and unrestricted grants from industry to clinical departments and faculty are used to fund research, department operations including food, clinical equipment, resident and fellowship training, CME programs, journal subscriptions, educational software, and support for attendance at meetings.[66] In a recent study, department chairs were asked to rate their departments' ability to provide independent, non-biased education (including CME) and training. The study indicated widespread recognition among responders that their departments' financial entanglements with industry had a negative impact on their ability to provide independent, non-biased education, depending on the type of relationship considered.[67]

In light of these multilayered financial relationships with industry, the medical education community has a heightened responsibility to develop and maintain robust conflict of interest standards.[68] The medical education community must provide appropriate educational opportunities to physicians-in-training, free from commercial bias. As a result, more and more academic medical institutions have implemented rigorous conflict of interest policies for departments and faculty. Additional policies have been created that restrict industry representative access to students, trainees and staff, on and off campus. In June 2008, the Association of American Medical Colleges ("AAMC") released a report recommending that academic medical centers establish standards for faculty and physicians, both on and off-site, that would limit such conflicts and mitigate the effects of these prevalent financial entanglements.[69] Specifically, the AAMC recommended that:

- Academic medical centers establish and implement policies that prohibit the acceptance of any gifts, including food and meals, from industry by physicians and other faculty, staff, students, and trainees of academic medical centers, whether on or off-site;

- Distribution of sample medications in academic medical centers be centrally managed; and

- Detailing by pharmaceutical representatives be limited to furthering educational goals.[70]

The AAMC also recommended that faculty should be:

- Discouraged from participating in industry-sponsored speakers' bureaus, except where academic investigators are presenting results of their industry-sponsored studies to peers and there is opportunity for critical exchange;

- Barred from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, industry or otherwise;

- Required to disclose all potential conflicts of interest and be recused from involvement in purchasing decisions in which there is a financial interest; and

- Permitted to enter into consulting arrangements or to participate on industry boards of directors and scientific advisory boards only when compensation for the services provided is set at fair market value.[71]

In sum, the recommendations are designed to assure that "moving forward, the overarching goal for both academic medicine and industry must be to maintain productive relationships in research, education, and patient care that contribute to the health of the public and sustain the public's trust."[72] Industry representatives have expressed support for many of the recommendations, although there has been considerable resistance to adoption of a directive that faculty and trainees avoid involvement in speakers' bureaus.[73]

Academic medical centers and teaching hospitals not only need to lead by example, but they need to devise curricula that will prepare physicians-in-training to distinguish promotional claims from evidence-based research.

Recommendation 15

Amend BME regulations to hold physicians, who are serving as faculty and preceptors, accountable to adhere to AAMC guidelines, both on and off campus.

Recommendation 16

Amend BME regulations to add a requirement that Medical Education Directors incorporate, as part of residency training, curriculum designed to teach residents to identify: (a) evidence-based data; and (b) conflicts of interest. Such instruction will permit residents to better assess the impact that the source of research funding may have on the value of the information presented.

VI. PHYSICIAN ACCOUNTABILITY

Physicians who participate in any paid activities on behalf of pharmaceutical and device companies should be prohibited from recklessly providing inaccurate or misleading information in an educational or promotional venue and should be required to completely and accurately disclose the nature and extent of their financial interests to the institutions at which they work and to government regulators. The BME regulations should make clear that physicians bear a responsibility to provide accurate and truthful information in any promotional or educational setting, including in medical school and residency training, as well as in professional publications. In addition, physicians should provide all required information about their financial interests so that the public, their

colleagues and regulators can evaluate whether their interest should be considered in evaluating their statements.

Recommendation 17

Amend BME regulations to prohibit physicians from recklessly providing inaccurate and misleading information in educational or promotional venues.

Recommendation 18

Amend BME regulations to prohibit physicians from claiming authorship of any article or study unless they, in fact, authored the work in question. Attribution should, however, be deemed appropriate if the physician supervised or reviewed the work of medical students, residents, fellows or researchers.

Recommendation 19

Amend BME regulations to prohibit physicians from misrepresenting financial interests in any required disclosure form, including through the omission of required information.

VII. HEALTH CARE FACILITIES

The New Jersey Department of Health and Senior Services ("DHSS") licenses certain health care institutions in the State. We have already discussed the conflicts that exist between physicians and industry in many scenarios. However, the mixture of industry, physician and health care institutions brings about additional conflicts that create impediments to unbiased medical decision-making. DHSS can play a key role in monitoring the activities of individuals working within these institutions to assess possible conflicts of interest with industry.

Academic medical centers, hospitals and other employers licensed by the DHSS should routinely and regularly inquire about industry interests. An assessment should occur to determine whether individuals with such interests should be in positions to establish formularies, make purchasing determinations, conduct clinical trials or participate on institutional review boards (IRB). Research shows a strong correlation between receiving industry benefits and favoring their products.[74]

A conflict of interest is created when a physician who has a financial relationship with a company sits on a purchasing committee considering the company's product or a competitor's product. This conflict could potentially lead to a purchase of a medical product based on personal interest rather than a sound medical decision that is in the best interest of the patient. Provisions should be adopted to assure that decisions are made that are in the best interests of the patients and the health care system. While some New Jersey hospitals currently mandate disclosure of interests, there is wide variability in what must be disclosed and to whom it is available.

Recommendation 20

DHSS is encouraged to promulgate policies and procedures that address the following:

- Creation of a standardized conflict of interest form for use by all New Jersey licensed health care facilities.

- Whether physicians with financial interests should serve on advisory bodies, such as formulary committees, purchasing committees or groups established to develop practice guidelines, or should conduct clinical trials or participate in IRB research.

- Whether disclosures of interests should be mandated in in-hospital educational venues before presentations begin (i.e. grand rounds, patient rounds and classroom).

- Creation of programs that allow community hospitals to ensure that the acceptance of industry funding for CME does not skew the message of educational sessions.

- Creation of a system to manage conflicts to avoid potential detriment to the safety of clinical trial participants or to the integrity of the research.

VIII. ACADEMIC DETAILING

Academic detailing is a method of outreach education that combines the interactive, one-on-one communication approach of industry detailers with the evidence-based, noncommercial information of academia. The term "academic detailing" reflects this hybrid concept.[75]

Academic detailing programs and other portals for dissemination of medical information are growing in number.[76] Recent evidence indicates that physicians are willing to participate in such programs to improve patient care.[77] In general, these programs work by sending a pharmacist, nurse or doctor (known as a "detailer") to visit a physician's office, just as industry would. However, the detailer is not sent to promote a certain product to the exclusion of all others, as opposed to an industry representative. In contrast, detailers discuss general medical issues with physicians. For example, the detailer and the physician may have a discussion about antibiotic resistance and the consequent need to prescribe antibiotics judiciously. Objective information would be presented on the "relative cost" and effectiveness of various treatment regimens. This discussion would ultimately serve to benefit the overall view of health care and treatment of patients.

Several states have studied or used academic detailing programs focused on therapeutic alternatives to high cost and/or overused Medicaid formulary drugs.[78] Disseminating commercial free evidence-based information has the potential of not only containing costs, but improving the quality of health care.[79] Academic detailing programs show considerable promise in effectively changing prescribing behavior. Objective sources of new product information, providing insight on the relative costs, benefits and risks for new and brand name products, as well as the older and generic products, would greatly assist physicians in making recommendations that are in the best interests of their patients.

Pennsylvania, in collaboration with Harvard Medical School, has developed academic detailing programs, through its Pharmaceutical Assistance Contract for the Elderly, the PACE/PACENET Program.[80] Pharmacists and nurses are trained to meet with doctors in their offices for ACCME accredited academic detailing visits. This program is completely non-profit and publically funded. Since its September 2005 launch, the Pennsylvania program has provided nearly 3,000 educational encounters, averaging 20 minutes each, with nearly 1000 practitioners.[81] Other models include industry funding of similar programs. Integrated health care systems, particularly Kaiser, have begun academic detailing programs. Programs of various sizes have been established or legislated in Pennsylvania, South Carolina, the District of Columbia, Vermont, New Hampshire and Maine.[82] Large scale programs are also being undertaken in several Canadian provinces, and in Australia.[83]

The concept of academic detailing is now being pursued on the federal level as well. On April 1, 2009 the Independent Drug Education and Outreach Act was introduced. This legislation, S.767 and H.R.1859, if enacted, would provide federal funding for academic detailing programs and the development of evidence-based educational materials. Academic medical centers and medical and pharmacy schools, as well as non-profit organizations, would be eligible for the grants under this bill.

New Jersey's practitioners and patients would greatly benefit from this approach to education. It would allow for educational opportunities outside of industry influence that would enhance health care treatment in the state.

Recommendation 21

Encourage the creation of academic detailing programs by amending BME regulations to require that a certain percentage of the required CME credits be derived from the completion of courses not subsidized by industry.

Recommendation 22

Explore grants that could introduce academic detailing programs in some DHSS regulated venues.

[1] *See, e.g.*, Niteesh K. Choudhry et al., *Relationships Between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry*, 287 JAMA 612-17 (2002); Ass'n of Am. Med. Coll. (AAMC), *Industry Funding of Medical Education: Report of an AAMC Task Force* (June 2008), available at https://services.aamc.org/Publications/showfile.cfm?file=version114.pdf&prd_id=232&prv_id=281&pdf_id=114; Robert Steinbrook, *Financial Support of Continuing Medical Education*, 299 JAMA 1060-62 (2008); Catherine D. DeAngelis and Phil B. Fontanarosa, *Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence*, 299 JAMA 1833-35 (2008).

[2] Benedict Carey, *Drug Maker to Report Fees to Doctors*, N.Y. Times, Sept. 24, 2008, at A18.

[3] Inst. of Med., *Conflict of Interest in Medical Research, Education, and Practice* www.iom.edu/CMS/3740/47464/65721.aspx., (last visited October 21, 2009).

[4] D.C. Code Ann. § § 48-833.01 to -833.09; Me. Rev. Stat. Ann. Tit. 22, § 1711E; Minn. Stat. § 51.461; Vt. Stat. Ann. Tit. 18 § 4632.

[5] *See generally* Michael J. Oldani, *Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales Practices*, 18 Med. Anthropology Q., 325-56 (2004).

[6] Troyen A. Brennan et al., *Health Industry Practices That Create Conflict of Interest*, 295 JAMA 429, 431 (2006); Jason Dana & George Loewenstein, *A Social Science Perspective on Gifts to Physicians From Industry*, 290 JAMA 252, 252 (2003).

[7] Brennan, *supra*, note 6, at 431.

[8] Dana, *supra* note 5, at 253, 254.

[9] Pharm. Research & Mfrs of Am. (PhRMA), *Member Company List*, www.phrma.org/about_phrma/member_company_list/members/, (last visited October 21, 2009).

[10] PhRMA, *Code on Interactions with Healthcare Professionals* (2009), available at www.phrma.org/files/PhRMA%20Code.pdf [hereinafter PhRMA Code].

[11] Advanced Med. Tech. Ass'n, *Code of Ethics on Interactions with Health Care Professionals*, revised and restated, (effective July 1, 2009), available at www.advamed.org. [hereinafter AdvaMed Code].

[12] PhRMA Code, *supra* note 10; AdvaMed Code, *supra* note 11.

[13] PhRMA Code, *supra* note 10; AdvaMed Code, *supra* note 11.

[14] PhRMA Code, *supra* note 10; AdvaMed Code, *supra* note 11.

[15] California: "Every pharmaceutical company shall adopt a Comprehensive Compliance Program that is in accordance with the April 2003 publication "Compliance Program Guidance for Pharmaceutical Manufacturers," which was developed by the United States Department of Health and Human Services Office of Inspector General (OIG). A pharmaceutical company shall make conforming changes to its Comprehensive Compliance Program within six months of any update or revision to the "Compliance Program Guidance for Pharmaceutical Manufacturers." Cal. Health & Safety Code § 119402 (Deering 2009)

Minnesota: "It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner. A medical device manufacturer that distributes drugs as an incidental part of its device business shall not be considered a manufacturer, a wholesale drug distributor, or agent under this section. As used in this section, "gift" does not include . . . items with a

total combined retail value, in any calendar year, of not more than $50…." Minn. Stat. § 151.461 (2008)

District of Columbia: "An individual shall be licensed by the Board of Pharmacy before engaging in the practice of pharmaceutical detailing in the District of Columbia." D.C. Code Ann. § 3-1207.41 (2009).

[16] Andrew Jack, *Merck to Publish GP Payments*, ft.com, September 23, 2009, www.ft.com/cms/s/0/f49fc0b0-a86c-11de-9242-00144feabdc0.html?nclick_check=1. The Physician Payments Sunshine provisions in America's Affordable Health Choices Act of 2009 (H.R. 3200, section 1451) and the Senate Finance Committee Chairman's Mark on America's Healthy Future Act of 2009 (title IV) would require drug and medical device manufacturers to report certain gifts and payments ("transfers of value") made to physicians and certain other entities. The information would be available in a single public website. Companies failing to report would incur financial penalties. The House bill was released July 14, 2009 in the House Committees on Energy and Commerce, Ways and Means, and Education and Labor. It was passed by Education and Labor and Ways and Means on July 17, 2009 and by Energy and Commerce on July 31, 2009. The Senate version was released on September 17, 2009. *See* The Prescription Project, *Bill Comparison: Physician Payments Sunshine*, http://www.prescriptionproject.org/tools/solutions_factsheets/files/Sunshine_HealthcareReform_10-09.pdf, (last October 21, 2009).

[17] PhRMA Code, *supra* note 10; AdvaMed Code, *supra* note 11.

[18] Kevin B. O'Reilly, *Drug Industry: No More Free Pens, Pads or Mugs*, amednews.com, July 28, 2008, www.ama-assn.org/amednews/2008/07/28/prl20728.htm.

[19] Julie M. Donohue, et al. *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 New Eng. J. Med. 673, 676 (2007).

[20] Adriane Fugh-Berman & Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0040150, (last visited October 21, 2009).

[21] Lisa D. Chew, et al. *A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior*, 15 J. Gen. Internal Med. 478, 479 (2000).

[22] IPSOS.com, *Is Direct-to-Consumer Advertising for Drug Samples Effective?*, www.ipsos-ideas.com/article.cfm?id=2139, (last visited October 21, 2009). *See also* Susan Chimonas & Jerome P. Kassirer, *No More Drug Samples?*, http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000074 (last visited November 30, 2009).

[23] Paul A. Rubin, *The Economics and Impact of Pharmaceutical Promotion*, 3 Econ. Realities in Health Care Pol'y 11 (2003).

[24] Jennifer Saranow & Amy Dockser Marcus, *The Higher Cost of Sneezing - As Nonprescription Claritin Hits Shelves, Insurers Jack Up Prices of Other Allergy Drugs*, Wall St. J., Dec. 10, 2002 at D1.

[25] Kaiser Family Found., *National Survey of Physicians* at 3 (2006).

[26] Lisa D. Spiller & Walter W. Wymer, *Physicians' Perceptions and Uses of Commercial Drug Information Sources: An Examination of Pharmaceutical Marketing to Physicians*, 19 Health Mktg. Q. 91, 99 (2001).

[27] *Id.*

[28] Robert M. Sade, *Paid to Prescribe?: Exploring the Relationship Between Doctors and the Drug Industry*, June 27, 2007, available at http://aging.senate.gov/events/hr176rs.pdf.

[29] Vt. Stat. Ann. Tit 18 § 4632; Minn. Stat. § 151.461; Me. Rev. Stat. Ann. Tit. 22, § 2698-A; Mass. Gen. Laws ch. 111N, § 2.

[30] D.C. Code Ann. § 48-833.03.

[31] H.R. 3200, sec. 1452, 111th Cong. (2009); Senate Fin. Comm., *Chairman's Mark: America's Healthy Future Act of 2009*, Senate Finance Committee, September 22, 2009.

[32] Troyen A. Brennan et al., *supra* note 6, at 431.

[33] D.C. Code Ann. § 48-833.03; Me. Rev. Stat. Ann. Tit. 22, § 2698-A; Minn. Stat. § 151.461; Vt. Stat. Ann. Tit 18 § 4632.

[34] United States Senate, Special Comm. on Aging, *Senators Welcome Endorsement from PHRMA, ADVAMED, Astrazeneca, and Merck of Physician Payments Sunshine Act*, http://aging.senate.gov/record.cfm?id=298258, (last visited October 21, 2009).

[35] *See Drug and Device Promotion: Charting a Course for Policy Reform, A While Paper by the Center for Health & Pharmaceutical Law & Policy*, Seton Hall University School of Law (Jan. 2009), pp. 13-18.

[36] *See supra* note 31.

[37] The following is a summary of the current state laws:

MINNESOTA: Minnesota law requires reporting of payments over $100 to physicians and bans gifts valued at $50 or more. The Minnesota and Massachusetts laws are the only statutes that include restrictions and make all disclosed data, including all physician-specific data, part of the public record. Unlike other disclosure laws, it does not require annual summary reports to the state legislature. Therefore, the state is under no obligation to analyze the data it collects. Thus, industry payment report forms had not been formally analyzed before an independent analysis was conducted in 2006. In order to be licensed, all wholesale drug distributors, including pharmaceutical manufacturers operating in the state, must comply with the law.

VERMONT: Vermont's law requires disclosure of payments of $25 and more. Due to a trade secret exemption, much of the data reported to the state is not made part of the public record. Annual summary reports by the Attorney General include average payment by prescriber specialty and type of service associated with payments. A penalty of up to $10,000 per violation of the law may be imposed. Recent amendments to the Vermont law, which became effective July 1, 2009, tightened the trade secrets exemption and closed other loopholes in the existing law.

MAINE: Maine requires disclosure of payments of $25 and over. Though physician-specific payment information is collected, it is not made publicly available. Payment information is made part of the public record only in the aggregate form. A fine of $1,000 for each violation of the law may be imposed.

DISTRICT OF COLUMBIA: Disclosure of all payments of $25 and over, including marketing, advertising and charitable contributions is required.

WEST VIRGINIA: West Virginia law requires disclosure of the total number of prescribers who have received payments over $100. No individual physicians are identified. Reporting of all marketing expenses is required, in addition to physician payments. There is no enforcement mechanism.

MASSACHUSETTS: Massachusetts law includes disclosure provisions and sets limits on certain marketing activities. This 2008 law establishes a mandatory code of marketing conduct that is "no less restrictive" than the PhRMA and AdvaMed Codes. It effectively bans the provision of non-educational and practice related items, caps the value of educational gift items to physicians at $100 and prohibits direct industry funding for physician attendance at professional meetings. While establishing the PhRMA Code as a baseline, the law allows the Department of Public Health to go further. Several provisions of the legislation, including limits on CME funding, go further than the Codes. The law also requires disclosure to the Commonwealth of all payments to a prescriber or health care professional by pharmaceutical and medical device companies valued over $50. The information is reported via a publicly searchable website. A penalty of up to $5,000 per violation may be imposed.

The Prescription Project, *Fact Sheet: Regulating Industry Payments to Physicians: Identifying & Minimizing Conflicts of Interest*, http://www.prescriptionproject.org/tools/solutions_factsheets/files/0006.pdf, (last visited October 21, 2009); Natasha Singer, *Doctor Gifts to be Public in Vermont*, N.Y. Times, May 20, 2009 at A1.

[38] N.J.A.C. 13:35-6.15.

[39] Guidance for Industry: Industry-Supported Scientific and Educational Activities, Fed. Reg. Vol. 62, No. 232 (Dec. 3, 1997).

[40] *See* Staff of the Committee on Finance United States Senate, Use of Educational Grants by Pharmaceutical Manufacturers: Hearing Before the Senate Committee on Finance, 110th Cong. (2007) ("Grants Report") (referencing "reports that pharmaceutical companies were routinely using educational grants to help build market share for their newer and more lucrative products.").

[41] Accreditation Council for Continuing Med. Educ. (ACCME) Annual Report Data 2008, available at http://www.accme.org/dir_docs/doc_upload/lf8dc476-246a-4e8e-91d3-d24ff2f5bfec_uploaddocument.pdf.

[42] Grants Report, *supra* note 40, at 16.

[43] *Id.* ("The documents provided by the pharmaceutical companies do not reveal an explicit agreement that the CME program will favorably discuss a company product or an off-label use of a company product. However, it is possible that both parties reasonably expect that to be the result.").

[44] R. Van Harrison, "The Uncertain Future of Continuing Medical Education: Commercialism and Shifts in Funding," *Journal of Continuing Education in the Health Professions*, Vol. 23 (2003): 198-209 ("CME providers generally recognize that they now have two important 'customers': the physicians who attend courses and the commercial companies that fund courses.").

[45] Ronald M. Cervero and Jiang He, *The Relationship between Commercial Support and Bias in Continuing Medical Education Activities: A Review of the Literature* (June 2008).

[46] Robert A. Musacchio & Robert J. Hunkler, *More Than a Game of Keep Away* (May 1, 2006), available at http://pharmexec.findpharma.com/pharmexec/article/articleDetail.jsp?id=323311.

[47] Adriane Fugh-Berman, *Prescription Tracking and Public Health*, 23.8 J. Gen. Intern Med. 1277, 1277 (2008).

[48] *Id.; See* http://www.ama-assn.org/ama/pub/about-ama/physician-data-resources/physician-masterfile.shtml, (last visited October 20, 2009). The AMA Physician Masterfile contains regularly updated demographic, education, licensure, specialty and certification information for all MDs and 90% of DOs licensed in the United States. AMA membership stands at approximately 30% of licensed US doctors. In 2005 the AMA received more than $ 44 million dollars from the licensing the AMA Physician Masterfile and its database products.

[49] Adriane Fugh-Berman, *supra*, note 47, at 1277.

[50] *Id.*

[51] Sean Flynn, *Litigation Challenging Regulation of Data Mining,* Program on Information Justice and Intellectual Property, American University College of Law, (March 31, 2008), available at http://www.wcl.american.edu/pijip/go/blog-post/litigation-challenging-regulation-of-data-mining.

[52] Posting of Daniel Carlat to carlatpsychiatry.blogspot.com, *Prescription Data Mining: A Transparent(-ly absurd) Defense by Verispan* (September 17, 2007).

[53] Kaiser Family Foundation, National Survey of Physicians Part II: Doctors and Prescription Drugs, Highlights and Chartpack (March 2002).

[54] Kevin B. O'Reilly, *AMA Opt-Out Program Will Keep Prescribing Data From Drug Reps*, AMNews, May 22, 2006, http://www.ama-assn.org/amednews/2006/05/22/prl10522.htm.

[55] *More Than a Game of Keep Away, supra* note 46.

[56] *Id*.

[57] *Id.*

[58] Jeremy A. Greene, *Pharmaceutical Marketing Research and the Prescribing Physician* 146 Annals of Internal Med. 742, 746 (2007).

[59] *Id*.

[60] Penelope Lemov, *The Prescription Proscription*, Governing Mag. January 1, 2008, http://www.governing.com/node/564/.

[61] IMS Health, Inc. v. Ayotte, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (2009); IMS Health, Inc. v. Sorrell, 631 F. Supp. 2d 434 (D. Vt. Apr. 23, 2009).

[62] IMS Health, Inc., 550 F.3d at 54, 58.

[63] PhRMA Code, *supra* note 10, at 13.

[64] Grants Report, *supra* note 40; AAMC *Industry Funding of Medical Education: Report of an AAMC Task Force, supra* note 1, at iii.

[65] Eric G. Campbell et al., *Institutional Academic-Industry Relationships*, 298 JAMA 1779, 1782 (2007).

[66] *Id.* at 1783.

[67] *Id.*

[68] *Conflict of Interest in Medical Research, Education and Practice*, *supra* note *3.*

[69] AAMC *Industry Funding of Medical Education: Report of an AAMC Task Force, supra* note 1, *at* 9-10.

[70] *Id*. at 14, 16-17.

[71] *Id*. at 20, 22-23.

[72] *Id*. at 31.

[73] *Id.* at iii, n.1.

[74] Michael J. Oldani, *supra* note 5*;* Jason Dana, *supra* note 6, at 252-55; Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283.3 JAMA 373, 373-80 (2000).

[75] The Indep. Drug Info. Serv. (IDIS), About Academic Detailing, http://www.rxfacts.org/detailing.php, (last visited October 20, 2009).

[76] *See* Univ. of Vt. Coll. of Med., Vt. Academic Detailing Program, http://www.med.uvm.edu/ahec/TB1+BL.asp?SiteAreaID=290, (last visited October 20, 2009); S.C. Coll. of Pharmacy, What is SCORxE?, http://www.sccp.sc.edu/centers/SCORxE/index.aspx, (last visited October 20, 2009); H.B. 1513-FN, 2008 Sess. (N.H. 2008), available at http://www.gencourt.state.nh.us/legislation/2008/HB1513.html; Mass. Gen. Laws ch. 111, § 4N; Me. Rev. Stat. Ann. tit. 22, §2682.

[77] F. May et al., *Experience with Academic Detailing Services for Quality Improvement in Primary Care Practice,*18 Quality and Safety in Health Care, 225, 225-31 (2009).

[78] Allan Coukell, BSc (Pharmacy), Director of Policy, Testimony *Before the Senate Special Committee on Aging: The Prescription Project Community Catalyst* (Mar. 12, 2008), available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Speeches/Coukell%20Aging%20Committee%20testimony%202008-03-10%20FINAL.pdf.

[79] *Id.*

[80] Pennsylvania's Academic Detailing Program, http://aging.senate.gov/events/hr190ne.pdf, (last visited October 20, 2009).

[81] *Id.*

[82] Allan Coukell, *supra* note 78; *See also, supra* note 76.

[83] *Id.*