

No. 11-204

IN THE
Supreme Court of the United States

MICHAEL SHANE CHRISTOPHER AND
FRANK BUCHANAN,

Petitioners,

v.

SMITHKLINE BEECHAM CORP.,
D/B/A GLAXOSMITHKLINE,

Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

**BRIEF *AMICI CURIAE* OF MEDICAL
PROFESSIONALS IN SUPPORT OF
PETITIONERS**

SARAH M. SHALF
Counsel of Record
Emory Law School Supreme
Court Advocacy Project
1301 Clifton Road
Atlanta, GA 30321
(404) 712-4652
sarah.shalf@emory.edu

(i)

QUESTION PRESENTED

Whether pharmaceutical sales representatives (PSRs) are “outside salesmen,” as defined in the Fair Labor Standards Act.

TABLE OF CONTENTS

	<i>Page</i>
QUESTION PRESENTED FOR REVIEW.....	i
TABLE OF CONTENTS.....	ii
TABLE OF AUTHORITIES	iii
INTEREST OF <i>AMICI CURIAE</i>	1
SUMMARY OF THE ARGUMENT	2
ARGUMENT	3
I. The decision to prescribe a drug incorporates a number of principal and controlling factors that leave little room for input from PSRs.....	3
A. The prescribing decision is tightly controlled by the nature of the drug in consideration and the individual circumstances of the patient.	3
B. Physicians derive much of the information they need from academic sources, colleagues, and guidelines and regulations. ...	4
C. Physicians utilize PSRs merely for supplemental information, thereby limiting external influence on decisionmaking.	6
II. Physicians’ prescribing decisions are governed by ethical considerations, the nature of which prohibits doctors from becoming mere buyers in a drug sales transaction.....	7
A. Physicians are ethically barred from interacting with PSRs as though they were buyers in a sales transaction because medicine is a practice, not a business.....	8

B. The medical profession has been pushing back against a sales transaction model of physicians' interactions with PSRs.....	14
CONCLUSION.....	18
APPENDIX: List of Amici Curiae	1a

TABLE OF AUTHORITIES

	<i>Pages</i>
Cases	
<i>Christopher v. SmithKline Beecham Corp.</i> , 635 F.3d 383 (9th Cir. 2011).....	8
<i>Jewel Tea v. Williams</i> , 118 F.2d 202 (10th Cir. 1941).....	7, 10
 Statutes and Regulations	
Department of Health and Human Services, Office of the Inspector General, <i>OIG Compliance Program Guidance for Pharmaceutical Manufacturers</i> , 68 Fed. Reg. 23731 (May 5, 2003)	17
Pub. L. 111-148 § 6002	17
 Other Authorities	
American College of Physicians, <i>Charter on Medical Professionalism</i> (2002).....	8-9, 13
American Medical Association, <i>Code of Ethics</i>	10, 11, 14
American Medical Students Associations, <i>PharmFree Curriculum</i> (2011).....	15
Avorn, Jerry et al., <i>Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians</i> , Med., Sci., and Soc’y, July 1982...	5
Brennan, Troyen A. et al., <i>Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers</i> , 295 J. Am. Med. Ass’c. 429 (2006).....	13-14

Brody, Howard, <i>Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry</i> (2007)	9, 10, 12, 13
Denig, Petra et al., <i>Scope and Nature of Prescribing Decisions Made by General Practitioners</i> , 11 <i>Quality and Safety in Health Care</i> 137 (2002)...	4
Fattore, Giovanni et al., <i>Social Network Analysis in Primary Care: The Impact of Interactions on Prescribing Behavior</i> , 92 <i>Health Pol’y</i> 141 (2009)	5
Goold, Susan Dorr & Mack Lipkin, Jr., <i>The Doctor Patient Relationship: Challenges, Opportunities, and Strategies</i> , 14 <i>J. Gen. Intern. Med</i> 26 (1999)	10-11
Hafemeister , Thomas & Sarah P. Bryan, <i>Beware those Bearing Gifts: Physicians Fiduciary Duty to Avoid Pharmaceutical Marketing</i> 57 <i>U. Kansas L. Rev.</i> 491 (2009)	10, 15
Heesters, Michael, <i>An Assault on the Business of Pharmaceutical Data Mining</i> , 11 <i>U. Pa. J. Bus. L.</i> 789 (2009)	6-7
Institute of Medicine, <i>Conflict of Interest in Medical Research, Education, and Practice</i> (April 2009).....	12
Katz, et al., <i>All Gifts Large and Small</i> , University of Pennsylvania Center for Bioethics Papers (2003)	15
Landefeld, C. Seth & Michael Steinman, <i>The Neurontin Legacy – Marketing Through Misinformation and Manipulation</i> , 360 <i>New Eng. J. of Med.</i> 103 (2009)	15

- Ljungberg, Christina, et al., *Hospital Doctors' Views of Factors Influencing Their Prescribing*, 13 J. Evaluation in Clinical Prac. 765 (2007) 4, 5, 6
- Manchanda, Puneet, *Pharmaceutical Innovation and Cost: An American Dilemma: The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 Yale J. Health Pol'y L. & Ethics 785 (2005)5, 6, 7, 17
- Mechanic, David & Mark Schlesinger, *The Impact of Patient Care on Patients' Trust in Medical Care and their Physicians* 275 J. Am. Medical. Ass'n 1693 (1996) 12
- Pharmaceutical Research and Manufacturers of America, *Code on Interactions with Healthcare Professionals*..... 16
- Rockoff, Jonathan D., *Drug Reps Soften Their Sales Pitches*, Wall Street Journal, (Jan. 10, 2012), <http://online.wsj.com/article/SB10001424052970204331304577142763014776148.html>..... 7
- Schumock, Glen T. et al., *Factors that Influence Prescribing Decisions*, 38 Pharmacoeconomics 557 (2004) 6
- Sexson, W.R. & Deborah Cruze, *Ethical Issues in Child Pyschiatry*, Am. Academy of Child & Adolescent Psychiatry News (December 2005).....9-10
- Studdert, David M., et al., *Financial Conflicts of Interest in Physician Relationship with the Pharmaceutical Industry Self-Regulation in the Shadow of Federal Prosecution* 351 New Eng. J. Med. 1891 (2004) 17

WHO Model Lists of Essential Medicines, World Health Organization, Mar., 2011, *available at* <http://www.who.int/medicines/publications/essentialmedicines/> 6

INTEREST OF *AMICI CURIAE*¹

Medical professionals submit the following brief to put forth the argument that, whether drug manufacturers consider PSRs salesmen or not, doctors simply cannot be “buyers.”

Physicians and doctors have a vested interest in ensuring that the law properly recognizes the relationship between PSRs, doctors, and their patients. Although PSRs seek to increase sales of their products, professional ethics and norms, as well as the necessary complexities of prescribing the right drugs for the right patients, demand that physicians use their best professional judgment when making a prescribing decision. The Department of Labor properly labeled the relationship as informational and educational, despite the undeniable bias of PSRs, but several courts, including the one below, have not reached the same conclusion.

Detailed information about amici is included in the Appendix.

¹ No party’s counsel authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici* or their counsel made a monetary contribution to fund its preparation or submission. Both parties were given timely notice of intent to file it. Petitioners have provided written consent to the filing of all *amicus* briefs and Respondent has provided written consent to the filing of this brief, both on file with the clerk.

SUMMARY OF THE ARGUMENT

There is no doubt that PSRs meet with physicians to further an agenda. However, the court below still was mistaken when it applied the Fair Labor Standards Act's relatively narrow "outside salesman" definition to the relationship between doctors and PSRs. While some courts have viewed those persuading intermediaries as salesmen, the court below ignores the complexities and intricacies of the doctor-patient relationship. That relationship is, at a bare minimum, much more complex than, for example, the one between someone selling car parts and someone with a car.

Physicians are bound by legal and ethical commandments when they prescribe medication to their patients. Those rigorous standards ensure that patients receive the safest, most effective, and timeliest care available. The public, therefore, is best served by doctors acting independently when making the prescribing decision.

Two principal forces make the prescribing decision unique among professional-client relationships. First, the prescribing decision requires a number of sophisticated, independent judgment calls that are left to the discretion of each individual physician. Second, physicians must adhere to ethical principles that require focusing only on the best interests of the patient when prescribing pharmaceuticals.

Therefore, the decision of the court of appeals should be reversed.

ARGUMENT

I. The decision to prescribe a drug incorporates a number of principal and controlling factors that leave little room for input from PSRs.

Modern medical literature makes it clear that physicians consider a wide variety of factors when deciding which drugs to prescribe for a patient. The complexity of the prescribing process, in combination with a doctor's obligation to tailor a drug regimen to the needs of an individual patient, renders the role of PSRs in influencing prescription decisions *de minimis*.

The foremost controlling factor in any prescribing decision is the individual needs of the patient. In addition, physicians glean much of the formative information for these individualized decisions from academic sources, their colleagues, local customs, and lists of recommended drugs. These primary decision-making factors functionally supplant the lower court's view of the PSR as a heavy-handed "salesman."

A. The prescribing decision is tightly controlled by the nature of the drug in consideration and the individual circumstances of the patient.

When prescribing a drug regimen for a patient, a doctor has two main concerns: how effective a drug will be to treat that patient's condition, and how safe the drug is to take. There are only a limited number of drugs available to treat any given condition, and a physician must weigh a given drug's safety, efficacy, and method of delivery against the other drugs in its

class before deciding that it is right for a patient. Much of the information a doctor relies upon comes from sources other than PSRs. However, PSRs can sometimes still be useful, provided the information they give is viewed cautiously.

The first thing doctors consider when prescribing a drug regimen is the regimen's likely benefits to a patient compared against its potential costs. See Christina Ljungberg et al., *Hospital Doctors' Views of Factors Influencing Their Prescribing*, 13 J. Evaluation in Clinical Prac. 765, 767 (2007); Petra Denig et al., *Scope and Nature of Prescribing Decisions Made by General Practitioners*, 11 Quality and Safety in Health Care 137, 142 (2002). Physicians balance the safety and efficacy attributes of potential drugs against each patient's variables. Ljungberg, *supra*, at 767. Doctors consider potential risks to the patient, including "drug-drug interactions, contraindications, allergies, and substance abuse." *Id.* Physicians also consider a patient's ability to take a drug, including whether that patient is likely see a drug regimen through to the end. *Id.* Individual patient needs, not a PSR's touting of his product's benefits, are the determining factor for whether a drug gets prescribed.

B. Physicians derive much of the information they need from academic sources, colleagues, and guidelines and regulations.

When deciding whether to prescribe a drug, physicians also tend to rely heavily on their personal experience with a specific treatment option. See Denig, *supra* at 142. Doctors develop this experience

in a number of ways, including through prescribing drugs as part of a clinical trial or during the ordinary course of practice. *See* Denig, *supra* at 141-42.

In the absence of personal experience with a drug, physicians turn to academic sources and clinical trials. *See* Puneet Manchanda, *Pharmaceutical Innovation and Cost: An American Dilemma: The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 *Yale J. Health Pol'y L. & Ethics* 785, 796 (2005); *see also* Jerry Avorn et al., *Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, *Med., Sci., and Soc'y*, July 1982, at 5-6. These, not information from PSRs, are the most popular and influential vehicle for disseminating information to physicians. Avorn, *supra*, at 5-6. In studies, academic sources were not only frequently cited as among the most persuasive sources of information, but are also nearly always cited among the most trusted sources of information. *See, e.g., id.*

Physicians also tend to rely heavily on the drugs and therapies frequently prescribed by their colleagues. Ljungberg, *supra*, at 767; cf. Giovanni Fattore et al., *Social Network Analysis in Primary Care: The Impact of Interactions on Prescribing Behavior*, 92 *Health Pol'y* 141 (2009). In some cases, physicians have even described coordinating with their colleagues to develop individual specialties, allowing each to stay up-to-date on literature in an effort to become the local expert on a specific matter. Ljungberg, *supra*, at 767.

Finally, physicians frequently receive information about guidelines and regulations provided by local,

regional, and national organizations. *Id.* at 767-68; Glen T. Schumock et al., *Factors that Influence Prescribing Decisions*, 38 *Pharmacoeconomics* 557, 558-59 (2004). Many organizations publish frequently-updated lists of recommended drugs (LRDs) that provide specialized review of drugs in a field of practice and make recommendations for different scenarios. See Ljungberg, *supra*, at 768. Large organizations such as the World Health Organization publish LRDs for emerging diseases in remote areas or based upon nuanced patient characteristics. See e.g., *WHO Model Lists of Essential Medicines*, World Health Organization, Mar., 2011, available at http://www.who.int/medicines/publications/essential_medicines/. Despite the wealth of information available to physicians in any type of practice, LRDs remain a valuable source of information because of their highly specialized nature and because they tend to incorporate the most up-to-date treatments available. Ljungberg, *supra*, at 767.

Because of the wealth of credible, up-to-date information available to physicians, PSRs have only a minimal effect on the prescribing decision.

C. Physicians utilize PSRs merely for supplemental information, thereby limiting external influence on decisionmaking.

Although PSRs are a stable presence in the medical world, their influence on the prescribing processes of most doctors is overstated. In fact, some doctors refuse to see PSRs for lack of time or benefit.

Cf. Manchanda, *supra* at 788-90. However, PSRs retain an audience with many physicians for one main reason: free information. PSRs find utility in doctors' eyes by providing ongoing education about emerging therapeutic approaches. Michael Heesters, *An Assault on the Business of Pharmaceutical Data Mining*, 11 U. Pa. J. Bus. L. 789, 820 (2009). Furthermore, accumulating studies show that doctors have become adept at extracting only the information they find relevant from PSRs. Manchanda, *supra*, at 5. Even pharmaceutical companies, including GlaxoSmithKline, have acknowledged this reality by compensating PSRs not by the number of prescriptions written in a territory, but by the positive reviews of the doctors they visit. Jonathan D. Rockoff *Drug Reps Soften Their Sales Pitches*, Wall Street Journal, (Jan. 10, 2012), <http://online.wsj.com/article/SB10001424052970204331304577142763014776148.html>. These indicators suggest any value of PSRs to doctors is found in PSRs' information dispensing capacity, not as "salesmen."

II. Physicians' prescribing decisions are governed by ethical considerations, the nature of which prohibits doctors from becoming mere buyers in a drug sales transaction.

In addition to the practical and legal prohibitions, ethical norms within the medical profession prevent physicians from acting as consumers or "buyers" when interacting with PSRs.

The court below unpersuasively equates PSRs with “salespeople in other fields.” *Christopher v. SmithKline Beecham Corp.*, 635 F.3d 383, 400 (9th Cir. 2011). In making that comparison, the court below relies heavily upon *Jewel Tea v. Williams*, 118 F.2d 202 (10th Cir. 1941), a case upholding the status of tea peddlers as outside salespeople within the meaning of the FLSA. The door-to-door tea salesmen in *Jewel Tea* and the PSRs in the present case certainly share a set of similarities—both cover specific geographic areas, closely monitor a small market, and seek to eventually improve the sales of their employers—but the court below misses at least one vital difference: that doctors filter their prescription preferences through layers of professional competency.

Physicians must first and foremost be concerned with the health and wellbeing of their patients. While they should consider the relative costs of drugs in the context of understanding a patient’s needs and insurance coverage, they do not make prescribing decisions based primarily upon personal financial interests.

A. Physicians are ethically barred from interacting with PSRs as though they were buyers in a sales transaction because medicine is a practice, not a business.

Medical ethics mandates that doctors approach their profession as a practice, not a business. A doctor’s first responsibility is to her patients, not her balance sheet. *See, e.g., American College of Physicians, Charter on Medical Professionalism*

(2002); Howard Brody, *Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry* 24 (2007). Nor is a physician free to create her own body of rules. Rather, physicians are expected to abide by a code of ethics recognized by the larger medical profession.

Physicians, therefore, cannot allow themselves to be swayed or enticed by sales pitches for medical products or drugs presented to them by PSRs. Maintaining physicians' ethical integrity is important because of the power gap that exists between patients and physicians, the importance of the trust society places in physicians to make ethical decisions, and the necessity of avoiding conflicts of interest.

1. *Maintaining physicians' ethical integrity is crucial to protecting patients.*

It is crucial that physicians consider only the needs of their patient when making any decision about prescribing drugs. According to the American College of Physicians, ethical practice "demands placing the interests of patients above those of the physician, setting and maintaining standards of competence and integrity, and providing expert advice to society on matters of health." *Charter on Medical Professionalism, supra*. Physicians must therefore be resistant to drug marketing schemes, and focus solely on the educational value of their interactions with PSRs. While they may learn from PSRs about how a particular drug functions, and ask questions about the drug, they should only focus on the drug's benefits in relation to their patients' needs. See W.R. Sexson & Deborah Cruze, *Ethical Issues in Child Psychiatry*, Am. Academy of Child &

Adolescent Psychiatry News (December 2005). Focusing primarily on other factors, such as pricing or promotional deals, which would be attendant to a normal sales transaction, is therefore inappropriate to physician's ethical responsibilities. This is markedly different from a transaction selling tea. *Cf. Jewel Tea*, 118 F.2d at 203-06 (describing tea sales transactions).

This duty doctors have to their patients derives in part from the "power gap" that exists between patients and doctors. *See Brody, supra* at 39. A doctor simply has more medical skills, knowledge, prestige, and understanding of a patient's medical condition than do most patients, and so the patient becomes dependent on the physician, leading to the need for strong ethical guidelines. *See id.* Some scholars have even called for this duty to be legally described as a fiduciary duty. *See, e.g.,* Thomas Hafemeister & Sarah P. Bryan, *Beware those Bearing Gifts: Physicians Fiduciary Duty to Avoid Pharmaceutical Marketing*, 57 U. Kansas L. Rev. 491, 492 (2009). The American Medical Association views ethical duties to the patient as so important that in situations where ethics and the law conflict, its ethical code demands that "ethical responsibilities should supersede legal obligations." American Medical Association, *Code of Ethics*, Opinion 1.01.

The need for such strong ethics is clear: while in a doctor's care, a patient is often vulnerable; he or she may be physically, emotionally, or psychologically dependent on the doctor's decisionmaking. Brody, *supra* at 25; *see e.g.* Susan Dorr Gould & Mack Lipkin, Jr., *The Doctor Patient Relationship: Challenges, Opportunities, and Strategies*, 14 J. Gen.

Intern. Med 26, 27 (1999). Drug prescriptions are a prime example of this kind of vulnerability and dependency. In prescribing a drug, a physician is telling the patient to ingest or apply to his or her body a chemical, possibly with uncomfortable or even dangerous side effects. The patient accepts this recommendation in the belief that the doctor would not proscribe this medication unless that chemical were effective at treating whatever ailment she is suffering and that that chemical is statistically and relatively safe for her to use.

In agreeing to take that prescription, a patient plainly submit to the best judgment of his or her physician. It is the doctor who has the knowledge and the skill to choose the drug, tailored to the needs of the patient, and it is the patient who must trust the recommendations of her physician. The doctor therefore must ensure that she makes decisions about prescribing drugs solely with the needs or best interests of her patients in mind. The American Medical Association Code of Ethics mandates that “[p]hysicians should prescribe drugs, devices, and other treatments based solely upon medical considerations and patient need and reasonable expectations of the effectiveness of the drug, device or other treatment for the particular patient.” AMA Code, *supra*, Opinion 8.06. Because patient need must drive every prescribing decision, ethically, a doctor must treat any presentation shared by a PSR as incidental to her own independent judgment and research.

2. *It is vital that society be able to trust physicians' ability to employ scientific knowledge and skill in their decisionmaking.*

It is vital to society that patients be able trust doctors. See Institute of Medicine (IOM), *Conflict of Interest in Medical Research, Education, and Practice 2* (April 2009). People cannot choose when and under what circumstances they may get sick, so they need to know that any physician treating them has the knowledge, skill, and ethical foundation to treat them in an effective and appropriate manner. Brody, *supra* at 25. Physicians “have a duty to uphold scientific standards, to promote research, and to create new knowledge and ensure its appropriate use.” *Charter on Medical Professionalism, supra*. The more the public perceives that physicians are easily swayed by sales pitches from the pharmaceutical industry, the more likely it is that social trust in physicians will erode. IOM, *supra* at 2; See also Brody, *supra*, at 24.

Society’s trust in the medical profession is grounded, in part, in the expectation that physicians will research and analyze the different procedures, treatments, and drugs they prescribe to patients. See David Mechanic & Mark Schlesinger, *The Impact of Patient Care on Patients’ Trust in Medical Care and their Physicians* 275 *J. Am. Medical. Ass’n* 1693, 1693 (1996). Educational presentations by industry PSRs are not a substitute a doctor’s ethical obligation to be fully informed about the drugs she is prescribing, nor may physicians treat them as such. Physicians must commit themselves to developing the quality of their care, which “entails not only

maintaining clinical competence but also working collaboratively with other professionals to reduce medical error, increase patient safety, minimize overuse of health care resources, and optimize the outcomes of care.” *Charter on Medical Professionalism, supra.* As potentially useful education tools, presentations put on by PSRs are not mere “sales transactions.”

3. *Physicians may not ethically treat meetings with PSRs as sales transaction because doing so would create a conflict of interest.*

The ethical duty owed by physicians to their patients must not be compromised by conflicts of interest. A conflict of interest can arise if a physician begins to feel responsible, whether through financial inducements, gifts, or otherwise, for helping a PSR boost his sales numbers. *See Brody supra*, at 29. Moreover, any situation that even has the potential to create a conflict of interest is unethical. *Id.* Therefore if doctors were to casually think of themselves as “buyers” or of PSRs as “salesmen,” it would start to erode the ethical protections meant to avoid just such a conflict of interest.

A study published in the Journal of the American Medical Association in 2006 highlights the concern in the medical profession over the conflicts of interests pose by PSRs in doctors’ offices. According to its authors, “[c]onflicts of interest between physicians’ commitment to patient care and the desire of pharmaceutical companies and their representatives to sell their products,” combined with strong market influences, are “posing extraordinary challenges to the principles of medical professionalism.” Troyen A. Brennan et al., *Health Industry Practices that Create*

Conflicts of Interest: A Policy Proposal for Academic Medical Centers, 295 J. Am. Med. Ass'n 429, 429 (2006). To have PSRs recognized as "selling" to doctors could only further those challenges.

As a prophylactic measure to deter PSR influence, the American Medical Association has stated that ethically "[p]hysicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products. Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier." *AMA Code, supra*, Opinion 8.06(2). Physicians committed to professionalism and ethics will therefore keep their decisionmaking regarding drug prescription patient focused. They will use PSR meetings only as an opportunity to learn more about the characteristics of particular drugs, and should not be swayed by consumer-oriented marketing pitches.

B. The medical profession has been pushing back against a sales transaction model of physicians' interactions with PSRs.

The medical profession clearly recognizes the potential hazard presented by PSRs, and it has taken several steps towards reducing the effect of sales representatives and to eliminate even the appearance of impropriety. The most significant changes include new ethical standards imposed by individual hospitals, regulations agreed to by pharmaceutical companies, legal requirements to increase transparency, and the growth of a culture of professional independence.

In spite of the ethical bars against prescription drug “sales transactions” in physicians’ offices, there has been a great deal of literature detailing the medical profession’s concern that interactions with PSRs have undue influence on doctors’ medical judgment. Studies have shown that even the giving of small trinkets, such as notepads and coffee mugs with company logos, by PSRs can influence physician’s prescribing patterns. *See, e.g.*, Katz et al., *All Gifts Large and Small*, University of Pennsylvania Center for Bioethics Papers (2003); *cf.* C. Seth Landefeld & Michael Steinman, *The Neurontin Legacy – Marketing Through Misinformation and Manipulation*, 360 New Eng. J. of Med. 103, 109 (2009). That such practices occur in the relationship between the pharmaceutical industry and physicians cannot be denied. However, it does not follow that unethical marketing practices are accepted by the profession as a whole, or that these practices should be encouraged by courts’ legal recognition of PSRs as “salesmen.”

Efforts within the medical community to counter the image of doctors as ready and willing buyers in supposed sales transactions with PSRs have been high profile. For example, the prestigious medical systems of Stanford, the University of California at Davis, Yale, and the University of Pennsylvania have all within the past five years instituted rules barring their physicians and residents from accepting any gifts, no matter how small, from PSRs. Hafemeister, *supra* at 517. The American Medical Students’ Association has also been proactive in discouraging medical schools from accepting educational money from pharmaceutical companies, and has been calling on medical schools “to implement curricula

that prepare students to interact with industry in a way that protects individual patients, promotes public health, and preserves the public trust in medicine.” American Medical Students Associations, *PharmFree Curriculum 2* (2011).

Even pharmaceutical companies have begun to shift their tactics in recognition that the proper relationship between PSR and doctor is one of education and information provision. As of 2009, the Pharmaceuticals Research and Manufacturers of America (PhRMA), which represents research-based pharmaceutical companies, has issued its own professional code which discourages industry representative from using sales techniques to pressure physicians into prescribing target drugs. The PhRMA code prohibits the practice of “gifting,” making it unprofessional for PSRs to leave even token gifts such as pens or sticky notes to doctors, while stating that “[n]othing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional’s prescribing practices.” Pharmaceutical Research and Manufacturers of America, *Code on Interactions with Healthcare Professionals* at 13. The role of PSRs, according to the PhRMA Code is to deliver “accurate, up-to-date information to healthcare professionals about the approved indications, benefits and risks of pharmaceutical therapies.” *Id.*, at 14.

At the same time, legal restrictions are also arising for the purpose of stemming unethical PSR influence on doctors. Starting in March, 2013, pharmaceutical manufacturers will be legally required to report all payments or transfers of value

to physicians that exceed \$100 in each calendar year, including honoraria, food, and travel. *See* Pub. L. 111-148 § 6002. Similarly, the Department of Health and Human Services has put out a guidance document warning doctors that accepting gifts of any sort from PSRs may violate the Federal Anti-Kickback Statute. *See* Department of Health and Human Services, Office of the Inspector General, *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003) (“[I]f the remuneration is intended to generate any federal health care business, it potentially violates the anti-kickback statute.”).

Doctors generally do not view themselves merely as commercial consumers of goods presented to them by PSRs. *See* Manchanda, *supra*, at 787. Evidence that practices such as “gifting” may influence doctors, or that the industry has engaged in marketing strategies that violate the ethics of medical practices, has raised red flags among the medical community, and has prompted calls for government and self-regulation of the industry. *See, e.g.*, David M. Studdert et al., *Financial Conflicts of Interest in Physician Relationship with the Pharmaceutical Industry Self-Regulation in the Shadow of Federal Prosecution*, 351 *New Eng. J. Med.* 1891, 1899 (2004).

The presence of these issues should not cause the courts to recast the relationship between physicians and PSRs as one of buyers and sellers. Indeed, to do so would undermine recognition of the necessity for doctors’ professional independence.

CONCLUSION

The decision of the court of appeals should be reversed.

Respectfully submitted,

SARAH M. SHALF
Counsel of Record
Emory Law School Supreme
Court Advocacy Project
1301 Clifton Road
Atlanta, GA 30321
(404) 712-4652
sarah.shalf@emory.edu

February 6, 2012

APPENDIX

List of Amici Curiae

Dr. Howard Brody. Howard Brody arrived at the Institute for Medical Humanities in May, 2006 to assume the position of Director. Previously, he was University Distinguished Professor of Family Practice, Philosophy, and the Center for Ethics and Humanities in the Life Sciences at Michigan State University, East Lansing. He served as Director of MSU's Center for Ethics and Humanities from 1985 to 2000. Dr. Brody received his M.D. degree from the College of Human Medicine, Michigan State University in 1976, and his Ph.D. in Philosophy, also from Michigan State University, in 1977. He completed a residency in family practice at the University of Virginia Medical Center, Charlottesville.

Dr. Brody has also written numerous articles on medical ethics, family medicine, and philosophy of medicine. Current research interests include the importance of an interdisciplinary humanities base for bioethics, ethical issues in primary care, community engagement in bioethics, and professional integrity in both medical practice and clinical research.

Dr. Brody was elected President of the Society for Health and Human Values (now part of the American Society for Bioethics and Humanities) in 1988-89. In 1993-94, Dr. Brody served as Senior Scholar in Residency for the American Academy of Family Physicians at the Agency for Health Care

Policy and Research in Rockville, MD; he also chaired the Michigan Commission on Death and Dying. In 1995, he was elected to the Institute of Medicine of the National Academy of Sciences. He has been invited to lecture in Great Britain, New Zealand, Norway, Denmark, Germany, Argentina, Japan, and China. His work has been translated into six languages.

Dr. Gregory Curfman. Dr. Gregory Curfman's career as a medical editor at the *New England Journal of Medicine* spans 26 years. He is currently the executive editor of the *Journal*, a position that he has held for 12 years. Prior to being appointed executive editor, he served as deputy editor of the *Journal* for 14 years. The *New England Journal of Medicine* is an international journal that has been published for over 200 years. It includes a wide range of articles and multimedia features across the spectrum of clinical medicine, basic research, health care policy, and ethics and health law. It has the highest impact factor of any medical journal.

Dr. Curfman is a board-certified internal medicine physician and cardiologist, and he is also an assistant professor of medicine at Harvard Medical School. He graduated magna cum laude from Princeton University, and cum laude from Harvard Medical School. He trained in internal medicine and cardiology at Massachusetts General Hospital and Brigham & Women's Hospital in Boston, and during his medical career he has served as director of the coronary care units at Brigham & Women's Hospital and the Dartmouth Hitchcock Medical Center. He also was medical director of the Cardiovascular

Health Center, a heart-disease prevention center at Massachusetts General Hospital.

He joined the editorial staff of the *New England Journal of Medicine* in 1986, where he now serves as the principal editor for cardiovascular disease. He also founded and directs the Perspective section of the *Journal*, which is the lead section of the *Journal* focused on issues at the interface of medicine and society. The conception and development of this section of the *Journal* stands as one of his signature accomplishments. A principal topic area covered in the Perspective section is health policy and health care reform, and Dr. Curfman has been responsible for the publication of many hundreds of articles and multimedia features in the health policy arena. Perspective articles are often covered in the public media, and many are included in the health policy curriculum at Harvard Medical School.

Dr. Curfman has written 60 editorials and Perspective articles for the *Journal* on a variety of topics in medicine and health care, including health policy, health law, and the regulation of drugs and medical devices. He has also given testimony before committees and subcommittees of the U.S. Senate and House of Representatives on the regulation and safety of medical devices. As executive editor, he was responsible for responding to subpoenas and undergoing legal depositions in relation to Vioxx product liability litigation. He communicates frequently with the public media, including the *New York Times*, the *Wall Street Journal*, and the *Boston Globe*.