

Physicians Against Drug Shortages (PADS)

VIA EMAIL

April 21, 2014

RE: Ethics Complaint
Against Prof. Eugene Schneller

Ms. Debra Murphy, Director
Office of Research Integrity & Assurance
Arizona State University
Tempe, Arizona 85281

Dear Ms. Murphy:

On behalf of Physicians Against Drug Shortages, a non-profit patient advocacy coalition, we're writing to lodge a formal ethics complaint against ASU Prof. Eugene Schneller stemming from his questionable "sponsored research,"ⁱ lobbying, and public relations activities on behalf of the U. S. hospital group purchasing (GPO) industry, the Healthcare Supply Chain Association (HSCA), its trade group, and Novation, one of the three largest GPOs.

This letter will document the fact that Prof. Schneller has engaged in serious academic and financial conflicts of interest involving this \$300 billion industry. In our opinion, his work for the troubled GPO industry is a flagrant violation not only of the American Association of University Professors guidelines on academic-industry relationships, but of ASU's own conflict of interest and ethics rules as well.

This matter also raises troubling questions about ASU's policies and procedures for overseeing faculty conflicts of interest in their sponsored research activities. Accordingly, we believe ASU has a moral and ethical obligation to publicly dissociate itself from Prof. Schneller's research. This letter will outline in detail potential options for addressing the harm he and his GPO clients have inflicted on our healthcare system, not to mention the potential damage to the reputation of Arizona State University.

Although we would have no objection to Prof. Schneller or any other academician conducting paid research for a commercial enterprise intended to help it improve, for example, its internal operations or marketing strategy, we have a serious problem with dubious "research" such as his, underwritten by a trade group, that is intended to promote that industry's harmful, self-serving public policy agenda.

This is no small matter. It has grave implications for patients, health care workers, and taxpayers--- in short, virtually our entire health care system. Before elaborating on Prof. Schneller's conflicts of interest, we'll explain our deep interest in this matter and why it is so urgent. The stakes couldn't be higher, in both human and financial terms.

Over the last 15 years, the GPO industry, which controls the purchasing of upward of \$300 billion annually in drugs, devices and supplies for some 5,000 private acute care hospitals, has been the target of investigations by the Senate Antitrust Subcommitteeⁱⁱ, and other federal and state agenciesⁱⁱⁱ; media exposes, including a prize-winning 2002 investigative series in *The New York Times*^{iv}; antitrust lawsuits^v; and independent academic studies^{vi}. These investigations, including testimony and documentation in four Senate Antitrust hearings, have produced extensive evidence of the industry's anticompetitive contracting practices, self-dealing, kickbacks, and conflicts of interest---practices that harm patients and health care workers by denying them access to the best, safest, and most cost-effective drugs, devices and supplies.

In the last several years, these questionable practices have given rise to unprecedented global shortages of generic injectable drugs. For a primer on this issue, read our op-ed in *The New York Times* of September 3, 2013, "How a Cabal Keeps Generics Scarce."^{vii} See also:

- *Baltimore Sun* of February 7, 2014, "GPOs fuel drug shortages"^{viii};
- *Buffalo News* of March 16, 2014, "Schumer defends system that creates shortages of critical prescription drugs"^{ix};
- *Clinical Journal of Oncology Nursing*, April 2014, Letter to the Editor.^x

Further, contrary to Prof. Schneller's specious sponsored research findings, independent empirical research and anecdotal evidence show that instead of sav-

ing money for hospitals--- their original and ostensibly their sole purpose--- these buying cartels actually inflate health care costs by at least \$30 billion annually.^{xi} History has shown, time and again, that competition and innovation reduce prices, whereas cartels raise them.

Indeed, the industry's current "pay-to-play" business model is itself a conflict of interest. It resulted from a misguided 1987 statute called the Medicare anti-kickback "safe harbor," which exempted GPOs from criminal penalties for accepting kickbacks from vendors---kickbacks that would be unlawful in virtually every other American industry. This may be the only American industry that has ever received a Congressional exemption from criminal prosecution. After the anti-kickback rules were implemented in 1991, GPOs abruptly abandoned their original mission to save hospitals money. Since 1910, when the first GPO was established as a buyer's cooperative, they had done so by obtaining volume discounts. GPOs covered administrative costs out of hospital dues, which the hospitals gladly paid because GPOs achieved tangible savings.

Under their existing business model, however, their goal is to maximize fee (a.k.a. kickback) revenue. And because GPO fees are based on a percentage of sales volume, the higher the price of hospital supplies, the more fees GPOs collect. These perverse incentives gave rise to a system in which vendors compete for exclusive GPOs contracts based not on who can supply the best product at the best price, but on who can pay the highest fees. In effect, vendors buy market share from the GPOs for exclusive access to their member hospitals. The more they pay, the more market share they receive. As a result, many vendors favored by GPOs enjoy monopoly status. For more documentation on GPO abuses, visit www.physiciansagainstdrugshortages.com, which will redirect you temporarily to www.puncturemovie.com. This site was created by the producers of *PUNCTURE*, a 2011 feature film, based on a true story, starring Captain America's Chris Evans.

Despite the incontrovertible evidence of GPO abuses, the GPO industry and its allies in Washington have succeeded in thwarting attempts by several right-minded members of Congress, including former Senators Herb Kohl (D-WI) and Mike DeWine (R-OH) of the Senate Antitrust Subcommittee, to repeal the anti-kickback safe harbor. That would have restored market competition to this industry. In our opinion, it would also have avoided the drug shortage crisis altogether.

Tragically, a 2005 draft bill circulated by Senators Kohl and DeWine to repeal the safe harbor never made it out of the Subcommittee.^{xii}

With that as backdrop, we'll address in detail our concerns about Prof. Schneller's questionable research.

Since 2009, his "research" has been a centerpiece of the GPO industry's public relations and lobbying campaign in Washington to preserve the "safe harbor" and its "pay-to-play" business model. In April 2009, Prof. Schneller published a "study" entitled "The Value of Group Purchasing- 2009: Meeting the Needs for Strategic Savings,"^{xiii} which he acknowledged was funded by the GPO trade group. [At that time, it was called the Health Industry Group Purchasing Association, or HIGPA. In 2011, HIGPA changed its name to the Healthcare Supply Chain Association, or HSCA, to obfuscate the group purchasing connection]. Despite Prof. Schneller's acknowledgment of the source of his funding, this disclosure has not mitigated the harmful impact of this research on efforts to reform the GPO industry. Unfortunately, in the fog of Washington, sound bites and campaign contributions count for more than facts and logic.

Not surprisingly, Prof. Schneller's study estimated that GPOs save hospitals about \$38 billion annually. Years after his study was published, HSCA continued to promote it, along with "sponsored research" by certain other academicians, as "independent studies" on its website, in press releases, and other communications. These communications included a November 19, 2012 letter to six senior members of Congress who had asked the GAO to investigate the role of GPOs in the drug shortages and the deadly fungal meningitis outbreak.^{xiv} Schneller's "study" is not scholarship. It is not honest, objective research worthy of a professor at a reputable university. This was a business deal.

Ignoring for the moment that this study, on its face, lacks any scholarly or research value, it also lacks credibility on various other counts, to wit:

- 1. The results are pre-determined and are not replicable by any independent, objective researcher.** The study contains no details on how the putative savings were actually calculated or how the hospitals were selected. The data were provided by a third party vendor, and the reader has no assurance of their integrity. For all we know, the GPOs could have

awarded bonuses or other incentives to participants for supplying data that would support their desired conclusion. Prof. Schneller's attempt to reassure readers about the credibility of his paper by stating that "various issues considered in the survey were reviewed by a group of industry experts nominated by the Health Industry Group Purchasing Association" is not persuasive.

2. **It fails to account for the savings that hospitals could achieve in an open competitive marketplace.** For example, when Masimo Corp., now the leading maker of pulse oximeters, was finally able to obtain GPO contracts and compete with Tyco Healthcare, the dominant supplier, the price of pulse oximeters plunged by more than 30%.^{xv} Masimo was awarded GPO contracts only after its story appeared on page one of *The New York Times*^{xvi} of March 4, 2002, after its CEO testified before the Senate Antitrust Subcommittee,^{xvii} and after it filed an antitrust lawsuit against Tyco Healthcare, now known as Covidien. Masimo ultimately received an award of about \$59 million, including legal fees.^{xviii} In fact, former GPO contracting executives, in separate interviews, have estimated that the kickbacks inflate supply costs by about 30%. If that monopoly premium were eliminated, the annual savings to our healthcare system could approach \$90 billion.

3. **Prof. Schneller's conclusions are unsupported by any credible, independent research and, in fact, are diametrically at odds with the findings of every known arms-length, independent study.** In an unusually bipartisan 2003 letter, Senators Mike DeWine (R-OH) and Herb Kohl (D-WI), then chairman and ranking member, respectively, of the Antitrust Subcommittee, dispelled the fiction that GPOs save hospitals money in warning the Defense Department against outsourcing its health care supplies procurement to GPOs. They wrote: "...savings figures that GPOs frequently cite as benchmarks to demonstrate savings are based on a manufacturers' list price that hospitals rarely, if ever, pay."^{xix} Other independent studies, media reports and investigations confirm their finding:
 - An April 2002 "pilot study" by the Government Accountability Office found that "GPOs' prices were not always lower and were often higher than prices paid by hospitals negotiating with vendors directly," in fact, "up to 39% higher than hospitals not using a GPO contract."^{xx}

- Prize-winning 2002 *New York Times* investigative series, "Medicine's Middlemen," revealed extensive GPO abuses, including anticompetitive contracting practices, self-dealing, and conflicts of interest;^{xxi}
- Although Prof. Schneller told the *Times* of March 4, 2002, presumably before he was hired by HIGPA, that '...the groups do provide benefits, although some hospitals can get good deals on their own,' he made no such acknowledgment in his study;^{xxii}
- *New York Times* of October 8, 2002 revealed that New York area hospitals "may be overpaying millions for medical supplies because their trade group [the Greater New York Hospital Association, or GNYHA] promotes a purchasing agent [Premier, Inc.] with financial ties to the group and at least one of its top executives..."^{xxiii}
- Investigation by the Senate Antitrust Subcommittee staff, including testimony and documents presented at four hearings from 2002 to 2006, confirmed the *New York Times's* findings, debunked GPO claims of cost savings and revealed other abuses;^{xxiv}
- *Los Angeles Times* of February 17, 2005 disclosed that the UCLA Medical Center was able to save about \$800,000, or about 6%, annually, on cancer drugs after it stopped buying through Novation, also one of the three largest GPOs;^{xxv}
- "Redefining Health Care," by Harvard Business School Professor Michael Porter and Darden School Professor Elizabeth Teisberg, who concluded in their landmark 2006 book that buying groups create "little or no" value and urged policymakers to "curtail anticompetitive buying-group practices";^{xxvi}
- "Group Purchasing Organizations: An Undisclosed Scandal in the U. S. Healthcare Industry,"^{xxvii} by Baruch College Distinguished Professor Prakash Sethi, who testified at a 2006 Senate Antitrust hearing that the voluntary code of conduct that the Subcommittee had demanded was worthless: "...I don't think this initiative amounts to any-

thing,” he said, adding that “It simply says ‘thou shalt be good, thou shalt not lie.’ They were supposed to do those things in the first place”;^{xxviii}

- Senate Finance Committee Minority Staff Report of September 24, 2010 sponsored by Sen. Charles Grassley (R-IA) concluded that there were no independent empirical data supporting GPO claims that they saved hospitals money;^{xxix}
- Study in the *Journal of Contemporary Healthcare and Policy* of fall 2011, which estimated, using empirical data, that hospitals would save at least \$30 billion annually if the GPO kickbacks were eliminated;^{xxx}
- And numerous hospital executives and purchasing managers have stated publicly that GPOs increase supply costs. Some of their statements are posted on www.physiciansagainstdrugshortages.com.

Until late January or early February 2013, HSCA had represented Prof. Schneller's 2009 study, as well as other "sponsored research," as "independent studies" on its website, www.supplychainassociation.com, even though the trade group was aware that this was completely false. That stopped only after Prof. Schneller was confronted with this fact in a January 23, 2013 phone conversation. Attached is a follow-up email to Professor Schneller of January 24, along with PDF files documenting the change from "independent studies" to "studies."

Not only was Professor Schneller paid for this research, but according to a document [attached] available on the web, he also has an ongoing financial relationship with Novation, one of the three largest GPOs. The document indicates that his "Research Consortium" is funded by a foundation created by Novation and named for its former CEO. Donors to the Mark McKenna Foundation are asked to "...mail checks to Eugene Schneller, Ph.D." We can only speculate on how these funds are used. In 2002, as CEO, McKenna was summoned to appear before the Senate Antitrust Subcommittee to respond to the panel's concerns about Novation's questionable contracting practices. Later, in response to a federal whistleblower lawsuit against Novation and Becton Dickinson (BD), the Justice Department launched a criminal investigation of Novation. The investigation,

which was first reported in *The New York Times* of August 21, 2004,^{xxx} apparently ended inconclusively.

Besides producing questionable research for his GPO clients, public documents show that Prof. Schneller is also a lobbyist for the GPO industry. Attached is a photograph, available on the HSCA website, showing him participating in a January 30, 2013 presentation sponsored by the HSCA for Senate healthcare staff at the Dirksen Senate Office Building.

As for the connection between anticompetitive GPO practices and the drug shortages, the Food and Drug Administration, after years of avoiding any public mention of GPOs in this crisis, finally acknowledged their central role in its October 2013 "Strategy for Preventing and Mitigating Drug Shortages."^{xxxii} Ironically, ASU alumna Dr. Marta Wosinska, director of the FDA's economics staff, also implicated the GPOs in her *Bloomberg Brief* of November 11, 2013.^{xxxiii}

In its initial report to Congress on drug shortages, released on February 10, the Government Accountability Office cited GPOs as a "potential underlying cause."^{xxxiv} As the request of six members of Congress, the GAO is conducting a separate investigation into the role of GPOs in the shortages and 2012 fungal meningitis outbreak. That report is expected this summer. And last month, the American University *Business Law Review* published "Pay-to-Play: The Impact of Group Purchasing Organizations on Drug Shortages,"^{xxxv} a highly critical analysis of the GPO system.

We think most academicians would agree that faculty at institutions of higher learning have a special obligation to be intellectually honest and fair-minded in conducting research and expressing their views on vital public issues. Prof. Schneller has clearly crossed the line from being an objective, unbiased student of group purchasing to being an advocate and apologist for this industry. That, of course, is what lobbying, public relations and law firms are for. We believe this is highly unethical and illustrative of the incestuous relationships that have developed in recent years between academia and industry in the medical-industrial-government complex. Instead of enhancing the reputation of Arizona State, Prof. Schneller's so-called research may prove to be a major embarrassment to your university, as troubling revelations continue to emerge about GPO abuses and their pernicious impact on our health care system. We can only wonder whether

Professor Schneller uses his paid research as instructional material in his classroom, or whether he produces this research solely as a money-making venture.

As noted previously, Prof. Schneller's activities violate ASU's own "ethical standards" [#5, "To practice intellectual honesty," and #6, "To prevent intrusion of subsidiary interests in the freedom of inquiry"] and constitute "unacceptable conduct" [#1, "Violation of canons of intellectual honesty," and #2, 'Engaging in activities where "conflict of interest" may influence the evaluation of, funding for, or general promotion of research proposals or research results'], as defined in Section ACD 204-1 of your Academic Affairs Manual.^{xxxvi} These guidelines echo the preamble to the American Association of University Professors'

"Recommended Principles & Practices to Guide Academy-Industry Relationships":

"To impart the results of their own and their fellow specialists' investigations and reflection, both to students and to the general public, without fear or favor . . . requires (among other things) that the university teacher shall be exempt from any pecuniary motive or inducement to hold, or to express, any conclusion which is not the genuine and uncolored product of his own study or that of fellow specialists."^{xxxvii}

Prof. Schneller has also violated your prohibitions against "employee endorsements of....political issues in a manner that indicates a connection to ASU or in any other way implies a university endorsement," as defined in the Staff Personnel Manual (SPP 813).^{xxxviii} Curiously, his biographical sketch in his 2009 study indicates that in an awkward attempt to conform to the letter of SPP 813, he has flouted its spirit. Noting that he was the "Dean's Council of 100 Distinguished Scholar in the School of Health Management and Policy where he is Co-Director of the Health Sector Supply Chain Research Consortium," he somehow neglected to mention that these schools are part of Arizona State University. Whether this omission was an oversight or intentional is for you to determine. Oversight or not, his January 30, 2013 presentation to Senate healthcare staff in support of the GPO industry leaves no doubt about his ASU affiliation. That presentation took place just over two months after House members requested the GAO investigation into the role of GPOs in the drug shortages. That was no coincidence.

Dr. Jeffrey Lacasse, a former assistant professor at the ASU School of Social Work, got it right when he wrote in *PLOS Medicine* of February 2010 that “Medical ghostwriting, the practice of pharmaceutical companies secretly authoring journal articles published under the bylines of academic researchers, is a troubling phenomenon because it is dangerous to public health.”^{xxxix} HSCA is not a pharmaceutical company, and Prof. Schneller has made no secret of who underwrote his study, but it has also proved extremely dangerous to public health.

Incidentally, in a recent case uncannily similar to this one, Dr. Christine Cassel, CEO of the National Quality Forum, was forced to resign in late February from the board of Premier, Inc., another big GPO, amid conflict of interest allegations. This was reported in *ProPublica*, the nonprofit investigative news outlet.^{xl}

We are confident that a thorough, arms-length inquiry by ASU will confirm our conclusion that Prof. Schneller has violated fundamental tenets of academic ethics and integrity. Although we strongly believe there is no place at a reputable university for a faculty member who has compromised himself to this extent, our goal is not to seek punishment. Our sole purpose in submitting this complaint is to seek to undo the damage he and his clients have done to American healthcare. Our efforts include prevailing upon the Obama administration and Congress to repeal the anti-kickback safe harbor and stop the drug shortages.

Accordingly, we respectfully call on ASU to *IMMEDIATELY* take the following actions:

- Publicly repudiate Prof. Schneller's 2009 study and require that he retract it, along with any other statements, articles, media interviews or presentations he has made in support of its conclusions;
- Publicly demand that he cease any further "sponsored research," lobbying, or public relations activities on behalf of the GPO industry and companies, trade associations, or other entities associated with it and terminate his financial relationship with Novation, HSCA, and any other GPO-affiliated entities;
- Require that he publicly apologize, in writing, to the ASU community for his violations of faculty ethics guidelines.

Full disclosure: *Physicians Against Drug Shortages is a grassroots patient advocacy group whose sole objective is to end generic drug shortages by restoring integrity and market competition to the group purchasing and hospital supplies industries. Our members are mostly anesthesiologists and critical care specialists who are outraged that they can no longer obtain reliable supplies of the drugs they need to properly treat their patients. We are all working on this project pro bono and covering expenses out of our own pockets. We have no vested financial interest in this issue.*

We would be pleased to discuss this matter with you further at your convenience and look forward to your response within 21 days. Please acknowledge receipt. Many thanks for your attention.

Sincerely yours,

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