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Web Roundup: Pharmaceuticals, 'Pharmascolds,' and Conflicts of Interest

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Over the past month, a number of researchers, institutions, and pharmaceutical companies have come under pressure for relationships between medical research, clinical treatment, and corporate profits. An investigation by the *New York Times* and *ProPublica* looked into Memorial Sloan Kettering Cancer Center's chief medical officer, Dr. José Baselga, who has since resigned, and his failure to disclose important financial relationships with pharmaceutical and health care companies when publishing the results of his breast cancer research. Medical journals and institutions require that individuals disclose those financial ties when they pose a potential conflict of interest for the work they are doing.

The same week, news broke that Richard Sackler, the former chairman and president of Purdue Pharma, is one of several individuals to patent a new formulation of buprenorphine for the treatment of opioid use disorder. Sackler, the son of one of the co-founders of Purdue, and his former company face more than one thousand lawsuits for what municipalities see as their role in the opioid crisis through the production and marketing of OxyContin. The Sackler family, whose name can be found on museums to art galleries to endowed university professorships, has had not only a profound impact on how opioids are prescribed but also revolutionized the very concept of pharmaceutical marketing. After criticism emerged following the new patent, sources familiar with the ongoing negotiations between the litigants now say that "doses" of the new version of the drug will be offered for free to people with opioid use disorder. The promise serves as a proposed pharmaceutical solution to a field of corporate pledges and donations from Purdue's peer companies and defendants.

This is far from the first scandal over research, pharmaceuticals, and profit. Others have accused manufacturers of the overdose-reversal drug, naloxone, of "profiteering from the opioid crisis," as drug prices soared alongside increasing U.S. overdose rates. As the *New York Times* story above points out, a number of cases a decade ago prompted similar outrage over conflict-of-interest policies, marketing, and corporate dollars, particularly within the field of psychiatry. At the time, Senator Chuck Grassley led a Congressional inquiry into a series of failures to disclose conflicts of interest among U.S. researchers. The perceived problem was

palpable everywhere from direct-to-consumer marketing to medical education, where a number of Harvard Medical students came forward to protest the lack of transparency in faculty industry ties among their medical school professors.

In response, Senators Chuck Grassley and Herb Koh proposed the Physician Payments Sunshine Act, the provisions of which were incorporated into the Affordable Care Act in 2010. This led to the mandatory reporting by medical product manufacturers of payments made to physicians and teaching hospitals and to the launch of the searchable Open Payments database. The database was subsequently used by the journalists above and several other research groups investigating transparency in medical research.

Over the past five years, parallel concerns have emerged about relationships between physicians and pharmaceutical companies in generating the opioid crisis. In the 1990s, professional organizations led by the American Pain Association began to champion a movement to better treat pain, adopting the language of "pain as the fifth vital sign" that has frequently been revisited today. Some of the physicians and organizations who advocated for the use of opioid medications as a way to take chronic, noncancer pain more seriously were later found to have received large consulting fees from the manufacturers of those pain medications. In 1986, Dr. Russell Portenoy, a former president of the American Pain Association and recipient of industry dollars, published in the journal, *Pain*, that he had found no evidence that opioids were addictive in noncancer pain. Others followed suit.

Both of these examples showcase a new set of questions emerging around the material production of research and medical treatment today. There is unprecedented pharmaceutical use as well as new drug categories of biologics in oncology and opioids in chronic pain and addiction treatment. As Jeremy Greene points out, the pharmacopoeia of the twentieth century cannot be solely reduced to corporate marketing, though it certainly plays a role. In the age of "disruptive" innovation and biotechnology start-up culture, there have been growing challenges to both the porous boundary between research and industry as well as to the system for conflict-of-interest reporting. The passage of the Bayh-Dole Act in 1980, which allowed universities rather than the federal government to pursue ownership of intellectual property arising from federally funded research, was a pivotal chapter in the pharmaceutical "biographies" of nascent drugs and devices.

Over the past forty years, the relationships between individual researchers, their home institutions, and the pharmaceutical or medical device industry have thus grown increasingly complex. Indeed, the sheer

size of the bureaucracies involved often leads to asymmetries of information sharing. Researchers report relationships to their institutions and to medical journals separately. Consumers of medical journal literature often have to actively access conflict-of-inflect disclosures on journal websites rather than directly available alongside article text. Medical device makers now record payments to researchers in an online system that journals say they do not have the staff or finances to routinely check prior to publishing their findings. Thus, the system of reporting of conflicts of interest to employers and journals functionally remains an honor system among providers themselves.

Critics of the conflict-of-interest regulations like Dr. Lisa Rosenbaum push back that we are too quick to assume the role of "pharmascold" in the "vicious gotcha cycle" of transparency-minded posturing. Though she distinguishes between the more egregious examples of industry-funded Hawaiian vacations, she notes that the moral condemnation directed at both prescribers and pharmaceutical companies alike can obscure "interactions characterized primarily by a shared mission to fight disease." Due to the absence of any one regulatory body or standardized reporting procedure, the regulations themselves can be less than transparent.

There exist varying degrees of nuance in the definition of conflicts of interest and the definition varies by source. Many might find the failure to report three million dollars of consulting fees is, for example, a different scale of accusation than one of putting an overly upbeat spin on a drug mentioned in conference proceedings, though these assumptions too are worth questioning. The means of recourse for violations of conflict-of-interest reporting and their utilization remain limited. Per the above investigation, though a three-year ban on publishing exists for researchers who violate the American Association for Cancer Research's disclosure policies, no author has ever been banned; in fact, more than one-third of oncology authors were found to have not properly reported financial conflicts of interest. Similar discrepancies between self-reported conflicts of interest and Open Payments data have been found among other medical specialties as well. Even health care journalism is having an internal debate about the role of conflicts-of-interest reporting among their sources.

None of these dilemmas will be solved overnight. From a social science perspective, many of us might question the very definition of "conflict of interest" today, when the production of research, knowledge, as well as pharmaceuticals is always contingent upon a messy set of Weberian bureaucratic rationalities and human self-interest. The fundamental questions to emerge for the research industries involve whose role such regulation might be and how, if we accept that out interests are always conflicted, an archaic system of self-policing might be better served by one

that acknowledges such contingencies and seeks to minimize them in ways that matter to both research and clinical practice.