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OPINION

Why I No Longer Consult for Drug Companies

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Consulting for any organization is a complex undertaking. It requires specific relationships among individuals that exist within a general organizational culture that itself may promote or discourage such relationships. Fundamentally speaking, a consultation occurs when an expert, usually from outside an organization, is brought in to provide expertise to the insiders or to help solve a problem(s) posed by the organization. Quite often, the relationship is time- or funding-limited and subject to confidentiality agreements (especially in the case of businesses). Physician–scientists who consult for the pharmaceutical industry seem both appropriate and even essential for the transfer of technology, and yet they are also problematic characters in the consulting game because scientists create potential intellectual property and because doctors write prescriptions. As I explain below, I have stopped consulting for the pharmaceutical and biotechnology industry for many reasons, including the influence of anthropology and specific anthropologists with whom I have collaborated on a diverse set of projects over the years.[1]

Twenty-five years ago, I began consulting for drug companies concerning what most people today call Alzheimer's disease (AD). In doing so, I identified and followed a specific strategy that was perhaps different from that of my colleagues of the time; rather than disparaging the pharmaceutical industry as an option for failed academics, I realized that very bright people could and would build careers in the industry, and I chose to try to identify the rising stars and work with them. For example, when I began my career, one of the dominant companies was Sandoz (now part of Novartis). The only product on the market to treat older people with so-called *cerebral insufficiency* was Sandoz's product, Hydergine. I was asked to

[1] To be disciplinarily fair, a few sociologists, particularly Drs. Jennifer Fishman and Susan Hinze of my home university also have informed my thinking.

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join the board of the Sandoz Foundation that awarded competitive grants to worthy scientific products. My wife and I also took a skiing trip with Bob Esner, the then-product manager of Hydergine in St. Moritz, Switzerland. Bob is now a senior executive of a company trying to produce a vaccine for Alzheimer disease (AD). He is a nice chap, has a Ph.D. in American history, and now talks publicly about his own family's concerns about AD.

My consulting career accelerated with the appearance of what became the first specific drug approved for Alzheimer. It was tacrine (Cognex) from Warner Lambert Parke Davis. I still remember the amazement I felt at being picked up by the Warner Lambert corporate jet while vacationing in Kitty Hawk, NC, of all places! Warner Lambert Parke Davis, itself an amalgamation of several companies, has now disappeared into the merger and acquisitions belly of Pfizer, the maker of the now market-leading Alzheimer drug, donepezil. Aricept (the brand name of donepezil; there is no generic) was developed by my favorite drug company, Eisai Inc. of Japan. Eisai has a corporate logo HHC that stands for Human Health Care, suggesting a more holistic concern for human wellbeing that goes beyond basic biology, a sentiment that I personally have tried to help them live up to. Eisai supported conferences on the harmonization of drug development in different nations, (Whitehouse 1997) as well as on on intergenerational learning and driving with dementia. Pfizer, Eisais'partner in selling donepezil in many parts of the world (and also a supporter of our harmonization efforts), aspired to be the biggest drug company in the world (perhaps an appropriate ambition for the makers of Viagra). Now that it has achieved this status, however, I wonder what its fate will be. Is it too big? Companies as big as Pfizer have difficulties producing enough products from the pipeline to support their huge infrastructure.

Over this 25-year span, I was a triple threat academic consultant in scientific, clinical and then organizational/ethical areas. I was, for a time, a world's expert on the cholinergic basal forebrain—a cluster of nerve cells that degenerate in people with aging brains and memories. My biological research identified acetylcholine's decline in the aging brain as a key element of the research that became the basis for the first drugs for AD, such as those mentioned above.

I conducted clinical trials with outcome measures (later in my career, I became an expert on quality of life measures, which the industry virtually ignored). I earned my Master's Degree in Bioethics and became increasingly concerned about conflicts of interest between doctors and drug companies, and then about the activities of bioethicists themselves (Whitehouse 1999).

In time, I developed national recognition through various National Institute on Aging Grants. I was invited to join the FDA advisory panel that eventually voted to approve tacrine, a later drug for AD (I was almost the only hold out). As part of my interest in improving global drug development, I founded the International Working Group for the harmonization of dementia drug guidelines. We endeavored to work with regulators around the world to make the processes of studying and approving drugs more uniform across national boundaries. Atwood Gaines, an anthropologist from my university, helped me understand the process by which we tried to come to consensus on various simple and non-controversial issues, and to how we

geriatricians and researchers avoided focusing on the difficult issues where there was little agreement.

In part, under Gaines' anthropological influence, my interests in the cultural aspects of Alzheimer disease intensified as my concerns about modern conceptions of Alzheimer's also grew. In 1998, I co-organized a conference in Dr. Alois Alzheimer's family home in Germany, which had been converted into a small conference center by one of my co-organizers, Dr. Konrad Mauer. This meeting of scientists, clinicians, social scientists, historians, philosophers and ethicists on the hundredth anniversary of the naming of the disease "Alzheimer's," led to a book entitled *Concepts of Alzheimer Disease: Biological, Clinical and Cultural Aspects* with Jesse Ballenger as the third editor in addition to Konrad (2000, the Johns Hopkins University Press). My success with this conference meant that Lilly Pharmaceuticals (who purchased the house) paid for the meeting and for dissemination of free copies of the book. Half a dozen humanities scholars flew back to the United States on the Lilly corporate jet, probably a rare occurrence in the annals of use for this form of luxury transportation. Continuing in the theme of examining cultural aspects of dementia, I organized an international group of anthropologists to explore how anthropology could contribute to our understanding of cognitive aging. This led to a paper published in *The Lancet Neurology* on the anthropological gaze and dementia (Whitehouse et al. 2005).

As more drugs came onto the market over the past decade (two more cholinesterase inhibitors and Memantine, an old drug used in Europe for over 20 years and, hence, a surprising entry into the modern field of medication treatments), my concern about being a KOL (key opinion leader) grew. I became interested in the management of KOLs by industry, and suspect that big pharma, as large drug companies are referred to, has extensive databases on all of us (after all, they have access to individual prescribing habits of every physician). I began to realize that they were trying to manipulate my opinion as much as I was trying to give them mine. I came to see that marketing was replacing science as the dominant conversation. Instead of questions about drug efficacy and patient benefit, I heard questions such as, 'How do we get doctors, especially primary care physicians, to prescribe more of our drug?' 'What do you think of our market position and our Direct to Consumer Marketing (DTCM)?' DTCM was one of the last straws in my decision that the industry would, indeed, go over the line to sell a drug. The practice would and does have patients asking physicians to prescribe a drug for them, a strategy that has been extremely successful in increasing the number of adverstized drugs. I also wondered why the prices for four drugs in the direct consumer purchase market were all quite similar. Where is price competition if the pharmaceutical industry is a model for the success of global capitalism?

I also saw that while we formerly developed drugs for diseases, the pharmaceutical industry had in fact switched to creating diseases for drugs. Companies looked to use-approved drugs for other conditions (this act is called "off label" prescribing and seems acceptable to me if there is a rationale for their use in different diseases than those for which it is originally approved *and* there are appropriate follow-up studies). In addition, new "disease" concepts emerged in order to support the expansion of markets for medicines. As concern about

Alzheimer disease began to spread, so did the proliferation of terms to label more mildly affected people who could be affected by extant pharmaceuticals. Concepts such as age associated memory impairment (AAMI) and mild cognitive impairment (MCI) were created. These 'new' stages or states, were in part, perhaps a large part, motivated by a desire to develop new drugs and sell more of the existing drugs. MCI was also invented as part of a strategy to try to go beyond existing symptomatic drugs to hoped-for, future disease-modifying drugs. The quest for powerful therapies, such as an amyloid vaccine, replaced the search for better neurotransmitter-based symptomatic drugs. Here in vaccine research, a problematic (in my opinion) drug company, Elan, enters the field. This appears to me as a very aggressive company whose financial viability may well depend on the success of the vaccine. This vaccine has caused some people harm, and even death, through an immunological difficulty that could have been predicted and monitored more carefully (in my opinion). The evidence for efficacy of this vaccine seemed puzzling and appeared to me to be over interpreted in a positive direction. As well, there are other foci in AD research that are problematic.

The non-cognitive symptoms of dementia, sometimes called BPSD (behavioral and psychological symptoms of dementia) are an incredibly broad set of features ranging from sleep disturbance to psychosis. These symptoms are distressing to patients, families and health care providers. They are best managed through psychosocial interventions. In my view, the term BPSD was in part created with significant industry support to foster pharmacological approaches; it represents another socially constructed entity that is ultimately unhelpful. Annette Leibing, an anthropologist, has helped guide my thinking about this topic. A soon-to-be classic case of disease construction is IEED (involuntary emotional expressive disorder), formerly known by the more obscure term PBA (pseudobulbar affect). This syndrome is characterized by spontaneous bursts of crying unassociated with much underlying affect. It is a rare symptom complex in AD but more commonly found in amyotrophic lateral sclerosis and multiple sclerosis. The term IEED was invented by a pharmaceutical company, Avanir (with the help of KOLs), to promote the development of an agent to treat this syndrome and to extend the market for their planned product. Of course, if it works in a more general population it might in fact improve quality of life in more people. But the drug is not as yet approved and concerns about long term safety have been raised.

My already growing concerns about the pharmaceutical industry were increased by safety issues with current drugs used to treat both cognitive and non-cognitive symptoms. It is shameful that we do not have a better system of post approval monitoring of safety issues. Companies began hiring a large number of consultants of different types and grades of importance—sometimes academics; sometimes high volume prescribers—to try to address the increasing monitoring of company/physician relationships with industry. About the same time, a whole genre of books emerged criticizing the influence of pharma over physicians, such as *On the Take* by Jerome Kassirer and *The Truth about Drug Companies*, by Marsha Angell. Moreover, specific anthropological studies such as *Prescribing by Numbers* by Jeremy Greene, *Picturing Personality* by Joseph Dumit, and *No Aging in India* by Lawrence Cohen emerged to challenge the power of science over culture and to note

the culture in the science. Finally, the prominent Harvard medical anthropologist and psychiatrist, Arthur Kleinman, started speaking broadly about conflict of interest being the greatest single current ethical issue in medicine—and I agreed.

In 2003, the pharmaceutical industry bought the US legislative branch for a few hours early in the morning when Congress approved a Medicare drug benefit for seniors without allowing the government to negotiate prices. The congressman who led the effort subsequently became the head of the main drug company lobbying group, and over a dozen legislative aids and other players joined the industry. Industry is spending too much money on lobbyists and on lawyers to sue generic drug companies to defend intellectual property in general and to sue researchers whose results are not positive for their pharmaceutical agents. They are not spending enough on making genuinely new and valuable chemical entities for those who need them, especially for those conditions called orphans-those with too few afflicted persons who could create a large revenue stream.

As the 100th anniversary of the first case of Alzheimer began to approach in 2006–2007, various other social science influenced projects emerged. A conference was held at Johns Hopkins University on the history of drug development and use in AD. A book entitled *Do We Have a Pill for This* is in preparation and derives from this conference, which was organized (once again) with historial of medicine Jesse Ballenger, who, with the publication of his book *Self, Senility, and Alzheimer's Disease in Modern America: A History*, emerged as a leading historian of AD. Finally, I have teamed with someone who is, no doubt, a future star of medical anthropology, Danny George (Oxford University), to pen *The Myth of Alzheimer's: What You Aren't Being Told about Today's Most Dreaded Diagnosis* This trade book is designed to open a conversation about the cultural and individual stories we tell about what we currently call Alzheimer disease. It reports in greater detail, than is possible to articulate in the present venue, our concerns about the influence of industry on our conceptions of brain aging, particularly pharmacological efforts, based on genomics, to prevent or cure the disease. It also attempts to offer new hope by attending to the narrative and cultural aspects of what I used to call Alzheimer's.

The promised productivity of genomic medicine has, for the most part, gone unrealized; most probably, it will remain so. Chronic "diseases" such as "AD" are too complex for simple molecular, reductionist therapeutic approaches. Experts, let alone laypersons, cannot fully understand the implications of susceptibility genes like ApoE4, that not only variably increase risk for AD and other neurological conditions, but cardiovascular disease as well (though it may protect against macular degeneration). Margaret Lock, another noted and influential anthropologist, has been studying my research group's genetic research on AD and has been most helpful in illuminating the challenges of constructing and coordinating lay and professional perspectives about understanding risk factors for AD. An issue made more complex by my view, and that of an increasing number of others, that AD is not one disease, but rather represents a heterogeneous mix of different conditions intimately related to brain aging itself. As Gaines and I have argued, AD may be seen as brain aging rather than a disease (Gaines and Whitehouse 2006). This epistemological shift also can help us regard dementia as a condition that has its origins because of events that take place across the continuum of life rather than

merely at the end of life, and can thus enhance our concept of "Alzheimer prevention". And, we must attend to the growing problem of environmental toxins, for our afflictions are not solely generated from within and outside of a socioenvironmental context, that can produce dementia—after all, we still poison our children with lead despite having known about its toxicity for centuries.

Eventually, governments, we hope, will recognize that fewer rather than all drugs are really useful and worth their cost. Perhaps professional organizations and individual physicians will curtail their unhealthy collaboration with the excessive medicalization of aging. There is an opportunity for the pharmaceutical industry to lead efforts to create sustainable healthcare. I am working with the Center for Business as an Agent of World Benefit at the Weatherhead School of Management at Case Western Reserve University to encourage businesses of all kinds, and particularly health-oriented businesses, to take the future of our planet seriously. Currently, our bodies contain numerous drugs to which we have been exposed in various ways. Studies show that drugs that pass through our bodies affect other species in various ecosystems (fresh water mussels are affected by fluoxetine, a psychiatric drug, for example). We are wreaking incalculable havoc on our ecosystems by producing excessive numbers of drugs and being careless with their distribution. The economic and ethical fragility of our pharmaceutical industry is an unrecognized threat to the US and world economy. The industry has been living off of unfulfilled promises and shady dealings for too long. Yet, it could reverse its history of unhealthy behavior and lead efforts into a less drug dependent and healthier future.

Ecological disasters as well as slow environmental deterioration will increasingly contribute to poor health of the world's people, especially children. Already, millions of children die each year due to lack of access to clean water. The health consequences of global warming will not so slowly begin to undermine our ability to seek unrealistic cures for chronic diseases of the elderly. Where is the pharmaceutical industry in considering the huge challenges that threaten our species and others?

I have earned over $50,000 of personal income per year (on average) for 20 years from the pharmaceutical industry and several millions of dollars in research and educational grants with my work in the Alzheimer field. I have recently moved as close to zero income as is possible from drug companies, but the pervasiveness of industry funding is so great it is hard to know how thoroughly it has been laundered through professional organizations and universities. I have stopped consulting for the pharmaceutical industry because I do not want to help them control not only our healthcare system but our very conceptions of health and illth.

Would I ever renew my efforts to help the industry? (I probably will not get the chance if they read this piece.) Perhaps I would like to help them reinvent their industry as a force for health rather than for selling pills. The pharmaceutical industry desperately needs a deeper ethical self-examination. I would sometimes say that I kept consulting to save the soul of industry, while endeavoring not to lose my own. This immodest claim recognizes, however, that physicians, including myself, tend to think they are immune to the influence of industry. Such a belief is empirically and culturally wrongheaded. However, a new relationship between

physicians and pharma could be a force for positive change in the world rather than a contributor to ethical and planetary decline.

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