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Panel discussion

Research, innovation, and safety: Doing the right thing

WHY BOTHER MANAGING CONFLICTS?

Ms. Totenberg: Dr. Pizzo, are the arguments from Dr. Stossel's presentation not realistic for Stanford University or other institutions? He states that there is no evidence of malfeasance and, although I could point out a couple of examples, certainly I would agree that doctors aren't on the take all over the country. They are not skewing their research deliberately to kill patients, so why bother managing conflicts?

Dr. Pizzo: The debate in some ways focuses on how information is presented and how it impacts the way we think about it. First, at Stanford, we are very focused on trying to engage in the appropriate interactions with industry. Long before I was part of the Stanford community, it built its reputation on a highly entrepreneurial, proactive environment that has indeed helped to stimulate biotechnology development in Silicon Valley and beyond. We want this process to continue, so I think there is a very important distinction to be made between interactions guided by scientific collegiality and appropriate discourse, which promote the kind of discovery to which Dr. Stossel and I referred, and the marketing strategies that are also employed.

We recognize that the pharmaceutical industry today invests more than $20 billion annually in marketing its products, much of it directed at physicians. This is not an accident: to the extent that physicians become marketing vehicles, pharmaceutical sales increase. While marketing may be appropriate in some cases, I don't think it's the right model for our students or for our clinical and related faculty to engage in. It's not what we are about. We want to educate our students about the world they will be entering, which balances the traditions of academia with the important realm of commercial activities. But we do not want our students and faculty to form their opinions about medications or medical devices based on marketing. Their decisions should be objective and evidence-based.

THE INFLUENCE OF GIFTS: DOES SIZE MATTER?

Ms. Totenberg: Do gifts from industry matter, even if they are small?

Dr. Pizzo: To think that there is no suasion as a result of small gifts is somewhat naïve. For instance, I recently read in Doris Kearns Goodwin's biography of President Lyndon Johnson that he had a practice of giving small gifts to people all the time. In fact, he often gave toothbrushes because he wanted the recipients of his gifts to think about him morning and night when they brushed their teeth. That's part of the strategy. Similarly, if you believe that small gifts don't influence prescribing behavior in some subtle way, then you are running against the tide of reality. There's no reason why we cannot or should not be able to have strong interactions with industry and at the same time recognize that we don't need to be engaged in the commercialization.

Ms. Totenberg: Dr. Vagelos, let me ask you the question from another point of view. What do drug companies want when they give those gifts?

Dr. Vagelos: Companies have measured the impact of gifts or they wouldn't spend the money on them. The question is what to do going forward. I personally looked at this issue very hard when I was CEO of Merck—not gifts specifically, but the question of what is optimal for interactions between sales representatives and physicians. Companies want to transfer information about their drugs; that's the good side because they want physicians to understand the bene-

Dr. Stossel reported that he has ownership interests in ZymeQuest, Inc., and in Critical Biologics Corp.; has intellectual property rights in Critical Biologics Corp.; has received consulting/advisory fees from Merck, Inc.; has received honoraria from Pfizer, Inc.; and has received royalties from Lippincott Williams & Wilkins. All other participants reported that they have no financial interests, relationships, or affiliations that pose a potential conflict of interest with this article.

fits and the risks. They are trying to get their sales reps time with physicians, so they have developed these gifts and other things that I am personally opposed to.

What is optimal? The two groups, academia and industry, should sit down and figure out the most effective way to transfer accurate information. I think that both groups would benefit from that type of meeting. The answer is not to unilaterally decide to prohibit interactions.

Ms. Totenberg: Dr. Stossel, the world of medicine has changed dramatically in the past 10 or 20 years, with academic medical centers' relationships with drug companies becoming institutionalized as a result of the 1980 Bayh-Dole Act. The news media are also entirely different now—they are not nearly as centralized, at least in broadcasting. And we live in a much more disclosure-oriented society. The somewhat sensational piece that I read at the start of this session was benign compared with what I could have written. It could have been much more destructive to Dr. Empathy and Rhode Island University Medical Center. The world of Jonas Salk does not exist anymore, and it seems as if you want to go back to a time that doesn't exist.

Academia is not operating in the real world. Medical students today think all this technology comes from Santa Claus.

—Dr. Stossel

Dr. Stossel: I absolutely agree that it's different. I'm not proposing a free-for-all; I'm saying that we need to understand the world we live in. Rather than making medical students take organic chemistry, they should take a course in democratic capitalism. Friedrich Hayek's wonderful book, *The Fatal Conceit*, describes how the market arose, and gifts were front and center. Do I really need to learn from the *Journal of the American Medical Association* that advertising works? Anybody who hasn't been in a coma knows that drug reps come with a gift because they are trying to sell you something.

I would argue that academia is currently not in the real world. Medical students now think that all this technology comes from Santa Claus. What are they going to think when we permit *less* interaction with industry during their training and then, once they get out in the community, often the only way they will get information about new products is from drug reps? I think we're setting students up to be out of touch.

I'm not saying we shouldn't have oversight; let's just stop the sanctimony. Many of the people who agree with me have been so terrorized by authorities in the media that they don't want to speak out.

Ms. Totenberg: Members of Congress believe they shouldn't have to disclose the names of their campaign contributors and that their votes aren't biased by lobbyist contributions, but their disclosure requirements aren't going to change.

Dr. Stossel: Doctors aren't government.

Ms. Totenberg: That's absolutely true, but we're talking about public perception.

Dr. Stossel: In government, politics and perception rule. In medicine and science, there is also plenty of politics, but if we allow perception to rule in this realm, the world becomes flat and medicine and science revert to a primitive state.

EDUCATION ABOUT NEW THERAPIES: IS THERE A BETTER WAY?

Dr. Pizzo: When it comes to educating physicians about new therapies and their side effects, I don't want to bifurcate information into that which comes from dispassionate sources versus that which might come from industry. Even under Stanford's new policy, we're not breaking off dialogue with industry. We're simply saying that it ought to be better governed by appointment, just as Dr. Vagelos has articulated. We have an entire program that educates students about how to receive and process information, both in medical school and once they go into practice, so that they'll understand how messages are being delivered and conveyed.

Given today's information technology, there is no reason why information about new drugs, side effects, or drugs in general needs to come from marketing reps. We live in a world where we can access information instantaneously in so many other venues and receive objective and insightful data. We ought to be using these venues rather than relying on marketing reps.

There was a story in the *New York Times* recently about how the marketing arms of pharmaceutical companies often hire individuals who are vibrant and exuberant—the cheerleader stereotype—as their sales reps.[1] They do so because it provides an entrée, a source of engagement. There's no doubt that it works, but I think drug companies can inform physicians about their products in ways that are much more objective and reasoned.

Dr. Vagelos: A better way to transfer information was something that I sought at Merck 15 to 20 years ago, at a time when I was, frankly, trying to eliminate the sales force. I set up experiments on information transfer minus

the sales force in one region, comparing the sales generated there with sales in another region. We tried to introduce new technology. We tried to force innovation in information transfer by saying that we were going to cut back the sales force by 15% or 20% per year. As you can imagine, that really traumatized the sales force, and I got no positive results from my experiments because they all were carried out through the sales force.

The only place where a concept like this could work is at a small company that comes up with an important new product. The small company would have no sales force and would announce that information about its product would be available only in regional meetings to be held around the country or around the world. This would revolutionize marketing and sales in the pharmaceutical industry, but it would require an important product that physicians want to learn about and a company that does not have an existing sales force.

Ms. Totenberg: Has there been a moment like that in the past?

Dr. Vagelos: Perhaps with the introduction of the statins in the 1980s, which were developed at the Merck research organization under my leadership. Drugs like the statins could have been introduced essentially without a marketing group, although maybe not at a big company like Merck. Launching a drug class that exciting, with that big of an impact on health care, could be possible without a sales force today because of the information technology we now have.

> **Launching a drug class as significant as the statins could be possible today without a sales force, given the info technology we now have.**
>
> —Dr. Vagelos

Ms. Totenberg: Realistically, however, that doesn't happen. At one time, you couldn't turn on the television without seeing a Vioxx ad, not to mention whatever was spent on detail reps for the drug. The marketing budget for Vioxx was humongous. This is the world as we know it.

Dr. Stossel: In a perfect world, there might be some repository of perfect information that you could access online. It just doesn't exist in this world. As a physician actively engaged in research, I like to think I'm looking for objective information that is reproducible, but I know that in research there is as much promotion as there is in industry. The idea that there is some objective source of information—a direct connection to God—is a conceit. So we have to accept that we're going to have to navigate through competing sources of information. When given a choice of who decides which information sources are available—either the market or wise authorities such as deans and department chairs—I'll take the market any day.

Dr. Pizzo: Some might say that the policies I've described are top-down positions, but those of us who work in academic medical centers know that there really is no top-down process because there are so many faculty with strong points of view. At Stanford, it took us a year of discourse to move to the policies that we're putting in place, and there is now uniform acceptance across our faculty that this is the right thing to do.

Ms. Totenberg: But there wouldn't be if you barred consultancy arrangements.

Dr. Pizzo: That's right, and so we're not barring consultancy arrangements.

BIG-TICKET INTERACTIONS: RESIDENCY FUNDING, TECHNOLOGY TRANSFER

Ms. Totenberg: Let's open up the discussion to the audience.

Comment from the audience: I was involved in developing the first conflict-of-interest statement for the American Academy of Dermatology as well as in efforts to prevent industry from funding dermatology residencies. My question is to Dr. Pizzo, because the department of dermatology at his university has a single residency now being funded totally by a drug company. Sixty-five percent of American Academy of Dermatology members think there is an insurmountable conflict of interest in such an arrangement, and I'd appreciate your comments.

Dr. Pizzo: This sponsorship of the residency by a pharmaceutical company started several years ago, at which time our faculty review group evaluated the idea to assess whether or not it was appropriate. The group felt it was a reasonable program to institute, so it went forth. We will continue to look at it, of course.* This case involved finding the right balance in the way we work with industry so as to promote the exchange of knowledge as well as Stanford's mission to bring forward discoveries that can be commercialized, which is a mission shared by other major academic medical centers. We will not succeed in our mission of translating discoveries if we try to do it in isolation.

* Editor's note: Dr. Pizzo has informed us that since the time of this conference, and in light of Stanford's new policies, Stanford has decided to discontinue this industry-sponsored residency.

We want to allow our residents and fellows to have appropriate kinds of interactions with industry so that they'll understand what's going on in the biotech and big pharma communities, which I think is an appropriate understanding to have. What I'm against is overcommercialization.

Ms. Totenberg: So the residency review committee at Stanford approved a residency that's fully funded by a company?

Dr. Pizzo: Yes. It is the only residency funded that way at Stanford.

Ms. Totenberg: Why that one, and why hasn't it been replicated? Usually something like that gets replicated.

Dr. Pizzo: This residency came about the way many things come about at Stanford, because a faculty member, in this case a department chair, made a proposal, and we looked at it objectively. I had my own personal concerns about it, but I asked others to review it as well. As to why it hasn't been replicated, I don't know—it just hasn't.

Ms. Totenberg: Regarding your point about commercializing discoveries, Stanford benefits financially when one of its scientists makes a discovery, does it not? Even though Stanford hands off the marketing, the university's legal department, which now has an intellectual property section, has patented their interest and the university stands to benefit, sometimes enormously.

> **The idea that there is some objective source of information—a direct connection with God—is a conceit.**
>
> —Dr. Stossel

Dr. Pizzo: That is correct, and this is an important issue. Stanford, the Massachusetts Institute of Technology, Columbia University, and a handful of other universities now have proactive offices of technology transfer and licensure and development, and it is now part of the culture that guides universities. We recognize that. There are two points I'd like to make. One is that the number of patents that have huge yields is very low. They're the ones that get all the attention, but there are hundreds if not thousands that fail or basically go nowhere. The second point is that we do technology transfer in a free and open way. There are some schools now that are aligning their academic promotions to faculty members' track record in getting patents. I think that is a misuse of scholarship because it skews things in a way that misses the opportunity for fundamental discovery.

THE PERSONAL VERSUS THE INSTITUTIONAL

Comment from audience: What I'm hearing today is that we think promotion and marketing are unnecessary and hence we want to restrict them, but we think innovation is necessary and we want to foster it. So we allow institutions to have relationships that fund big-ticket items like residencies, fellowships, and research, but we are going to restrict pens and pizza. I see an inconsistency there. They are either both acceptable or both evil.

Dr. Vagelos: That's a very good point. My response is that one is personal and the other can be done through an institution. I would recommend that companies go to institutions and give money to the dean's office, for instance, to fund fellowships or scholarships. The dean's office and the faculty would then decide where to put that money. That makes the funding impersonal and does not suggest undue influence on prescription writing, whereas the pizza that is delivered by a sales rep does.

Dr. Pizzo: That is precisely the way the Stanford guidelines are set up. We leave open the opportunity for educational support to come from industry so long as it goes through a central source.

Dr. Vagelos: But there has to be a payback. No company is going to put money into a medical center and get nothing out of it. You'll have to provide an alternative, such as the scheduled meetings that I suggested.

Ms. Totenberg: Will people go to those meetings? I mean, detail reps show up at the office and sometimes doctors just see them to get rid of them. If there were that kind of informational meeting, and presumably it would be huge because there are tons of products, how would doctors know which booth to go to? It seems like a great idea, but how would it work?

Dr. Vagelos: That is why I suggest that industry get together with the academic medical centers and figure out how to make it work. The faculty, after all, want to be kept up to date. They want to learn about new methods of treatment, so if there are good, credible speakers on a regular basis, and if companies are scheduled to be present at certain times, I think it could be done. It just has to be worked out and the culture has to change.

CODEPENDENT NO MORE?

Ms. Totenberg: Dr. Pizzo, it's one thing for Stanford, Yale, or the University of Pennsylvania to ban gifts, as they all have fairly large endowments. But what about

other institutions that don't have huge endowments and rely on money from drug and device companies to fund fellowships? How can you get residents to go to informational lunches if you don't provide the lunches? Lunches cost money, and fellowships cost a lot more money.

Dr. Pizzo: One of the fundamental premises is that Stanford is well off because it is well endowed, but it costs us a lot to run these programs and it will cost us a lot not to have these additional funding sources. In fact, the cost is in the hundreds of thousands of dollars up to over a million dollars per year, so we too recognize the limitation.

Over the past year, as we were working out the details of our new policies, what I heard most often from faculty was, "This is the right thing to do and we really support it," coupled with a statement like, "But I don't know how I'm going to run my seminar series." This speaks to the fundamental problem: a codependency has developed. And that, I think, is the fundamental issue we are addressing.

DRUG SAMPLES: BAD? GOOD? DEMEANING?

Question from audience: I'd like the panel to talk about free drug samples. Should they be banned?

Dr. Pizzo: At Stanford, we have our free drug samples sent to our pharmacy and then distributed for use at the free clinics that we run. I think it's clear that drug companies use free samples as a strategy for marketing the most expensive drugs by getting physicians and patients hooked on them as opposed to generics. I'll be much happier when pharma is handing out free samples of generics.

Ms. Totenberg: Dream on.

Dr. Stossel: As there are more generics, it will happen. In the real world, doctors like samples. A lot of physicians and their office staff can only afford to take short lunches—20 or 30 minutes—so when the drug rep comes in with samples, the staff gets a quick and convenient lunch. This has a lot of appeal to harried docs who feel they couldn't run their offices without it.

Dr. Vagelos: I think that samples are demeaning to the sales reps. A better model would be to deliver samples to the central office of an academic center so that they get to poor people, which is something industry wants, of course. The idea of needing samples in order to get to see physicians suggests that physicians are not anxious to simply get the good information that's available from reps. So both sides have been complicit in the way this has developed. We need to come up with a new paradigm.

Technology transfer and licensure is now part of the culture that guides universities.

—Dr. Pizzo

DOLLARS AND THE DRUG DEVELOPMENT PROCESS

Question from audience: In its new recommendations on clinical and translational research, the Association of American Medical Colleges is going to recommend that medical schools and residencies incorporate research as a core competency. The idea is that our physicians, not to mention the general public, may not be entirely literate in the scientific process and may not be able to determine whether a claim is, in fact, a breakthrough. This was pointed out in a recent *New England Journal Medicine* article by Alastair Wood, who argued that breakthrough drugs are rare and that both the drug approval process and market incentives favor the development of "me-too" drugs.[2] In this context, we have all these claims of breakthroughs and the marketing that goes along with them. I would like Dr. Stossel to clarify whether he's arguing that there is no problem or that our solution to it is laughable.

Dr. Stossel: The latter. Life isn't perfect. There are saints and there are serial killers among us, with most of us in between. And anybody who hasn't been in a coma now realizes that there is concern about conflict of interest. Consciousness has been raised. Let's just keep things in balance and not slap on a lot of discriminatory and confining regulations that aren't helping.

Dr. Pizzo: There are some people who always do the right thing, regardless of the rules, but most of us need a sense of the rules of the road. We're just trying to provide guidance on appropriate behavior.

Question from audience: Dr. Vagelos described a series of events during drug development, with each stage of development posing potential conflicts of interest. We know that clinical drug development is an inefficient process—many compounds enter the process but few finally succeed, so that development is like a pyramid with a wide base of potential drugs and a few successes at the top. Separately, someone else mentioned the figure of $20 billion spent on marketing. Is more money spent at the end of the development process, on marketing the drugs that are approved, than on grants to universities to support early-phase research?

Dr. Vagelos: About equal amounts of money go into research and development versus marketing and sales. A relatively small amount goes into grants and contracts because the great majority of funding for basic research is within the industry, whereas the bulk of funding for clinical research goes to academia.

Question from audience: How does the money devoted to clinical trials compare with the money for postapproval marketing?

Dr. Vagelos: I don't know exactly, but certainly clinical trials are the biggest expense component of research and development. Of course, marketing and sales is another world unto itself, one that is also very big, and that's what has to be changed, frankly.

Dr. Stossel: An undercurrent that I'd like to address is the common perception that pharma doesn't innovate, that it produces only me-too drugs and from then on it's all marketing. Breakthrough drugs come along at unpredictable times. If you don't have the money from marketing the me-too drugs, you aren't going to develop those innovative drugs. If, as a public relations stunt, we tell pharma to stop marketing, the pharma companies will start downsizing and go into the dog food business, and we will end up with fewer drugs.

The disclosure system is limited by the reality that people perceive the truth in different ways.

—Dr. Pizzo

Dr. Vagelos: I will remind you that at Merck, between 1975 and the end of 1994, we introduced the first important drug for glaucoma, timolol (Timoptic); the first important drug for Parkinson disease, carbidopa-levodopa (Sinemet); the statins; the first drug for osteoporosis, alendronate (Fosamax); and the first recombinant vaccine in the world for hepatitis B. It goes on and on. It's a matter of having the research organization. Do you have the proper culture? It can be done without me-too drugs.

Dr. Pizzo: There have been challenges since that time. It's important to note that today it costs anywhere from $800 million to $1.2 billion to develop a drug. It's a huge investment, and many drugs do fail. If one critically looks at the pipeline of new agents, it's not as robust as one would like. The real action is not happening as much as one would like at big pharma; it's happening much more in the biotech arena, where more risks are being taken. Because industry has become so big and has such a great need to support itself, of course it's going to have to market its products aggressively, and of course there are going to be a lot of me-too agents. It's a risk-averse environment as a result of these huge financial concerns.

COULD BETTER PEER REVIEW MAKE DISCLOSURE MOOT?

Question from audience: I wonder whether the excessive disclosure that Dr. Stossel referred to earlier is a reflection, in part, of the failure of the peer-review system. If we had a better ability to assess data and better access to the data that have been controlled by the pharmaceutical companies that sponsor some of the research, would it be less incumbent on researchers to make disclosures? Clinical trial data are closely guarded by companies; almost all clinical trial agreements have required surrender of data ownership to the pharmaceutical companies. That's one aspect of the issue. The other is that people assume that the peer-review system does, in fact, assess data to the point where the data can be deemed credible or not. Ultimately, isn't the purpose of conflict-of-interest management to assess and assure that the data coming out are, in fact, legitimate and not skewed because of someone's personal interest?

Dr. Stossel: Peer review is fine as far as it goes, although the people who worship it are the ones who live off of it. Its greatest value is that when you prepare to publish, you know that those nasty competitors are going to give you a hard time, and so you try to get your act together and do as well as you can.

As for disclosure, it has become a public relations tactic. I don't understand the policy of the *Journal of American Medical Association*, which says that *relevant* conflicts must be disclosed. But then it goes on to say that basically anything that in the future might make you money must be disclosed. Then there are the people who call out that you didn't disclose the slice of pizza you took from the drug rep.

Dr. Pizzo: Part of the challenge is whether disclosure always reflects reality, and this cuts back to the point made earlier, which is that we're dependent upon people telling the truth. People perceive the truth in different ways, which is a limitation of our system. At the end of the day, we rely on honesty and self-reporting to determine whether or not we're getting the information. Some have argued, even at our institution, that we ought to be looking at outside sources, including income tax returns. I'm against moving in that direction.

HOW TO HANDLE SPECIAL ON-SITE TRAINING NEEDS?

Comment from audience: One thing we haven't talked about today is that some forms of medical innovation, particularly novel devices, require that doctors receive special training to learn how to use them safely. For novel devices like this, the FDA requires that the manufacturer conduct physician training as a condition of market approval. This inevitably requires a nexus of interaction between the manufacturer and physicians and patients, not just in the classroom but at the bedside or in the operating suite. I'd like to know how Stanford's new policies address these types of situations.

Dr. Pizzo: At Stanford we do have device vendors come in and participate in education directly in the operating rooms, and we plan to continue allowing that to happen. It's selected by appointment, so that we know that someone from the vendor is going to come. Because they are there for educational purposes, we value this type of interaction and see it as not representing a conflict that gets in the way of our due process.

MISSING THE BIGGER PICTURE?

Comment from audience: With all due respect, I think this discussion is mostly about pulling weeds when the forest is rotten. When young people decide to essentially sacrifice their youth to go into medical training, they expect to receive a decent salary. Not necessarily an exorbitant salary, but a decent salary. When they enter practice, there is no compensation for teaching and education, there is no benefit to practicing ethically, and the overall reimbursement for services is down. I think that's the crux of the issue. In the old days, when the drug reps came to my office, they wanted me, as a physician, to buy something from them. It is now the other way around: we physicians want the drug reps to finance what we're doing. The day has come when I, as a colorectal surgeon, receive more money if my patient is in a clinical trial than I do for removing a rectal cancer. That's the corruption in the system, and until that's dealt with, the higher-echelon discussion isn't going to impact the doctor on the front line.

Dr. Pizzo: You are speaking to another important issue that's not the topic for today. The United States is the only developed nation in the world that doesn't have a universal health care system, and that's part of what you're addressing. We're number one, best as I can tell, in only one thing, and that's administrative overhead.

Ms. Totenberg: It always strikes me as peculiar, as someone who lives in Washington and watches the body politic, that doctors are in a frenzy about tort reform but are not in a similar organized frenzy about reimbursements under Medicare, Medicaid, and similar programs.

REGULATE THYSELF, DOCTOR—OR BE REGULATED UPON

Ms. Totenberg: We need to proceed to the next session, but I'd like to make a closing observation. Part of the reason that the medical profession is having such a rough time in this area right now, I think, is exactly what the colorectal surgeon from the audience has just said. Salaries are going down and private medical practices are suffering more. Even at academic institutions, people increasingly are looked at in terms of the research they can bring in, the number of operations they perform, and whether or not they can essentially pay their own salary.

> **Medicine is the only profession that is still unregulated from the outside in terms of its conflict-of-interest rules.**
>
> —Ms. Totenberg

Yet medicine is the only profession that still is widely admired by the public and that is unregulated, in terms of ethics, from the outside. Even federal judges, by law, must disqualify themselves from any case in which they have even one share of stock. Yesterday, I filed a story about new rules that the Judicial Conference of the United States adopted for all federal judges. The rules bar judges from receiving reimbursements for expenses when they attend a seminar unless all the donors that have funded the seminar are fully disclosed publicly.

In contrast, the medical profession is still completely unregulated from the outside in terms of its conflict-of-interest rules. My suspicion is that if the profession fails to come to some sort of consensus about how to regulate itself from the inside, eventually it too will be regulated from the outside.

REFERENCES

1. **Saul S.** Gimme an Rx! Cheerleaders pep up drug sales. New York Times; November 28, 2005.
2. **Wood AJJ.** A proposal for radical changes in the drug-approval process. N Engl J Med 2006; 355:618–623.