Interview with Dr. Marcia Angell, former Editor-in-Chief of the New England Journal of Medicine

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ABSTRACT

Abstract— Dr. Marcia Angell is an American physician, author, and the first woman to serve as editor-in-chief of The New England Journal of Medicine. She is currently on the faculty of the Department of Global Health and Social Medicine at Harvard Medical School in Boston, Massachusetts. She has written a number of influential works on the healthcare industry and large-scale pharmaceutical business practices. The following is a transcription of the interview conducted by Michael Reaves with Dr. Marcia Angell.

Keywords: bioethics, Affordable Care Act, New England Journal of Medicine, interview, government

INTRODUCTION

Dr. Marcia Angell is an American physician, author, and the first woman to serve as editor-in-chief of The New England Journal of Medicine. Dr. Angell joined the Journal's staff in 1979, became executive Editor in 1988, and served as Editor-in-Chief of the journal until June of 2000. She is currently on the faculty of the Department of Global Health and Social Medicine at Harvard Medical School in Boston, Massachusetts. Her most popular work, The Truth About the Drug Companies: How They Deceive Us and What to Do About It (2004), is critical of big industry in healthcare and its role in research and medicine. In April of 2016, I had the opportunity to sit down with Dr. Angell for a discussion about some of the most controversial topics in healthcare economics, regulation, journalism, and politics.

I solicited Dr. Angell's opinion on a recent decision regarding pharmaceutical companies, Amarin Pharma, Inc. v. United States. This decision holds that the First-Amendment protects off-label drug promotion by pharmaceutical companies. Dr. Angell indicated that it is difficult to prove that unethical behavior occurs in the promotion of off-label drugs because it is hard to monitor the behavior. She believes there will not be much success in the prosecution of individuals responsible for pushing these marketing strategies, and that jail time will likely be the only deterrent in an industry that incurs fines as a cost of doing business.

I asked Dr. Angell about the Journal's recent policy changes regarding conflict of interest. The current Editor of the Journal, Jeffery Drazen, has loosened the conflict of interest policy, which now allows authors of editorials and review articles to receive up to $10,000 from each drug company. Dr. Angell holds firm that a zero-tolerance policy, or no allowance of payment between companies and writers, is the only way to eliminate conflict of interest in medical journalism. She discusses why the policy change is problematic and may incentivize unethical promotions.

In the conclusion of the interview, Dr. Angell discussed how, in her view, Obamacare will unravel if not altered or amended. She blames the Affordable Care Act (ACA) for not limiting provider profits, arguing that

deregulation is the biggest driver of increasing costs – a step in the wrong direction. Dr. Angell argues that the ACA is not a sustainable model for healthcare delivery and that a non-profit single-payer system should be our healthcare goal – especially in comparison to other, more successful healthcare systems worldwide. Given the recent presidential election of Donald Trump, there is growing uncertainty about what will become of the ACA. Only time will tell.

ANALYSIS

Q: Good afternoon, Dr. Angell. Let me begin at the beginning. Why did you get into the medical profession?

A: I was passionate about it. I was swimming against the tide, because when I went to medical school, women didn't do that. If you were going into science, you were going to get a Ph.D. and do research, and for a while I thought I would do that. I was interested in virology. But from the time I was a small child, it seemed to me that the worst thing that could happen to anyone was to be seriously ill. I always had that feeling. I did not grow up in an intellectual or scholarly household, so among the few books in the house that I read and enjoyed reading was the Red Cross Manual of First Aid. I read that a lot. I wanted to take care of sick people and I didn't want to be a nurse. For a while I thought I would be a medical technologist, and then as I went through college I got more ambitious, and I decided I would do graduate work in virology. I was nibbling around the edges, and finally I thought, no, becoming a physician is what I really want to do, so I did.

Q: During your lecture on death and dying, you indicated that your specialization was pathology after medical school. What made you choose that route?

A: My parents did not send me to medical school, and these were the days when it was possible to send yourself, but you had to do a lot of work to do that. The chairman of the Pathology Department at Boston University School of Medicine (BUSM) had a very successful textbook in pathology. His name was Stanley Robbins. He asked me whether I would read for him. He always did that with each edition of his book. It was a bestselling book, and one of his tricks was to get a student to read and tell him what was understandable, and what wasn't – to help him with it. I was doing well in his class, and when he asked me whether I would read for him, I did. Later on, he decided to create a smaller, more clinically oriented textbook, and he asked me whether I would be a co-author. Together we created this book, and the first edition was in 1971. It was called Basic Pathology.[1] The textbook came out, I had done two years of a residency in internal medicine, but I hadn't gone any further than that. I wasn't a pathologist; I was basing the clinical aspects of this book mainly on what I'd learned as a resident in internal medicine. When it was time for me to finish my residency -- by then I had two children, I wanted to be a nephrologist -- a kidney specialist. When I came back to the fellowship, one of my daughters had been very ill the night before and I was up all night with her, and then the other one woke up in the morning, and I realized that if I had to take care of living patients, I just couldn't do it. So I decided to go into pathology because you didn't have living patients and nobody could make the point that there's an emergency that you have to tend to. You would do autopsies or look at specimens after surgery. I had also written a textbook in the subject, and so I was able to get one year of credit for that. So I did my residency in pathology really on the basis of this book that I had worked on and created with Robbins. I went at it backwards when I became a resident in pathology. I was using my own textbook, which was really kind of odd.

Q: How long was the gap between residency and your time with the New England Journal of Medicine?

A: There were two residencies at BUSM – the first was in internal medicine. Then I spent several years out, working on the book and having babies and taking care of them. I finished the first residency around '69; then I went back and I did the residency in pathology beginning in '77, so about an eight-year gap between the two residencies. I was in my second residency when my late husband, Arnold Relman, took over as editor of the New England Journal of Medicine, which would have been in '77. I had known him in medical school. In fact, Stanley Robbins, Arnold Relman, and I wrote a paper together when I was an intern that was published in the New England Journal of Medicine, so I knew both of them. He, Relman, and I had some contact over

the years, and Relman hired me to work at the New England Journal of Medicine in 1979. I was still doing my residency in pathology; I hadn't finished that yet. So when I came to work, I worked part-time at the Journal and part-time finishing a year's residency, which I did in two years. Work for women in those days was just made up as you went along. It was like Mao Tse-tung said, you just seize the moment. Relman said to me, "Ok, you can do this half-time thing for one year, but at the end of the year you have to go one way or the other. Either you come full time to the New England Journal of Medicine and give up your textbook," because I'd done a third edition of the textbook, "or you go into pathology. It was a difficult decision, but by the end of the year I really loved being at the New England Journal, so I gave up the textbook. Somebody else took over my part of that.

Q: I am a big fan of your late husband, Arnold Relman. I read his paper on the medical-industrial complex[2] when I was 15. In 2011, he stated that the Journal lacked discretion in approving particular publications, and specifically mentioned a case regarding the blood-thinning drug, Warfarin.[3] From reading your book on the pharmaceutical industry, I know that you have issues with conflict of interest impeding ethical research and the delivery of drugs.[4] Did the flaws in that study change the legitimacy of the study in general? The new editor-in-chief, Jeffery Drazen, loosened the journal's conflict-of-interest policy that your late husband set forth. How do you feel about that move?

A: I recently wrote an op-ed about that in the Boston Globe.[5] The Boston Globe published a front page story, saying a lot of the criticisms that both Bud (Arnold's nickname) and I had was the weakening the conflict-of-interest policy that Bud put into effect. After Bud retired, his successor, Jerome Kassirer continued his strong conflict-of-interest policies for the eight years that he was there, and I then continued for the one year I was editor-in-chief. All three of us continued the most stringent conflict-of-interest policies of any medical journal. When Drazen came in, one of the first things he did was to weaken them. In recent years, he has been arguing essentially in favor of conflicts of interest as though the pharmaceutical industry and academic medicine were in the same business somehow, and we ought to support each other. So this created controversy about Drazen's policies -- policies that neither Bud, nor I, nor Jerry Kassirer approved of.

The Boston Globe asked me whether I would like to respond to this article. I said I would like to respond, because conflicts of interest are not a mere nicety; there's a reason for them. One of the biggest problems, among many, is that if industry-supported research does not find a benefit of the drug, the results are never published; they're put into a black hole. Only positive studies are published, creating the impression among both doctors and the public that prescription drugs are much safer and more effective than they really are. So this was a part of Bud's objection to the studies on these new Warfarin replacements. They have a serious side effect in that they can't be reversed. If you're taking these drugs and you start to hemorrhage, there's nothing that can be done about it. Whereas if you're taking Warfarin, hemorrhage can be reversed with vitamin K. Bud experienced that first hand in 2013 when he fell down the stairs in our front hall and broke his neck. The bleeding from the fracture compressed his windpipe, and he had three cardiac arrests. If you're an admirer of him, you ought to read his piece in the New York Review of Books, where he wrote about this experience. It was published in 2014, called "On Breaking One's Neck," and it's seen through the point of view of a patient who was not thought to survive.[6] It was a terrible, terrible accident, with the cardiac arrests. He was 90 years old, and he did survive. He took Warfarin for atrial fibrillation, and he would not have survived if he had been taking one of the newer drugs, because the first thing they did was to give him a lot of vitamin K to reverse the Warfarin. So the criticisms of the study were exactly right, he would not have published it, nor would I. He experienced the worst side effect of these drugs. They have no particular benefit and exhibit significant risk.

Q: Drazen argued that your husband's policy was one that has constrained editors from publishing the best possible information for doctors, but he seems to put a number value on what is acceptable in terms of financial ties to authors. The new policy allows drug companies to pay a writer $10,000 annually for editorial reviews. Yet, writers may receive payments from multiple companies, and a company may pay more than one writer, which gives writers multiple sources of income and thus presents a conflict of interest. Given this, is any amount acceptable? Do you think there should be a zero-tolerance policy?

A: Zero. People are very odd in how much money they consider trivial and how much they don't. Also, it creates a kind of misleading collegiality between senior faculty members, the kind of people who write these particular types of articles -- editorials and review articles. In terms of the original articles that contained primary data, no, we just disclosed conflicts of interest. We didn't forbid them. But we prohibited

them for the authors of articles that had no original data and relied solely on judgment and opinion, and said that no conflict of interest is OK in these cases. It throws the burden on the reader to discern whether the author was biased or not. It rewards senior faculty for having financial ties to not just one but multiple companies whose fortunes are influenced by their work. One person said that what the senior faculty really likes, in addition to money, is food, friendship, and flattery, and you see how that works and how that co-opts people who think they're objective and who want to be objective, but who are in fact so closely allied with the big drug companies that they start to feel their pain. (laughs) So we felt that this was where we were going to hang tough.

Q: A decision in the Southern District of New York in August of 2015, Amarin Pharma, Inc. v. United States,[7] held that First Amendment protections for true or factual speech in off-label drug promotion is permitted. The case concerns the FDA's ability to forbid drug promotion for off-label use. The court held that prohibiting truthful speech in off-label promotion is a violation of the First Amendment. Does this open the door to more unethical behavior in the industry?

A: There's absolutely no way to tell whether off-label promotion is truthful, because there are no data. If there's no evidence, who is going to say what is truthful? Everything depends on the quality of the evidence. If there were evidence, they would have gone to the FDA to get it labeled, to have it approved. So this is how they sell drugs that cannot get approval. The Court's decision is absurd because it shows ignorance of how you would know whether the promotion is 'truthful or misleading.' It's clearly an industry-sponsored decision.

Q: Turning to industry, I wanted to discuss a recent case in the last year. Johnson & Johnson (J&J) was caught pushing Risperdal on unapproved patient populations.[8] When there are key cases like this, it seems that the added First Amendment protections would exacerbate the problems that exist already.

A: Absolutely. Even so, even before this decision, I suspect that they would appeal. Even before this decision, I think J&J were fined around six billion. That's just the cost of doing business. It's dwarfed by the profits they make from these illegal activities.

Q: J&J was fined $2 billion in penalties back in August, and some people estimate that that may go up to $6 billion.[9] However, they've made up to $30 billion on Risperdal both domestically and abroad. It's a drop in the bucket. It's almost as if we are incentivizing criminal behavior: the profit that drug companies receive far exceeds the penalty of the fine that they'll have to pay, like you said.

A: Yes. If you look at any of the big drug companies, I think every one of them, I can't think of one that hasn't been successfully prosecuted for fraud, and many of them, I think J&J was one, admit criminal charges. They get a fine that's hundreds of millions or a few billion, pay it, and do the same thing again. They agree to some compliance activities and repeat the behavior. That's what they do in their business, and business is good.

Q: The CEO of J&J, Alex Gorsky, was awarded a social responsibility award by The Appeal of Conscience Foundation, an interfaith organization, one month after the outcome of this case.[10] He had a direct connection to the management of the Risperdal account. Do you think he was aware of often-illegal strategies put forward to push the drug on vulnerable populations?

A: Yes.

Q: So how do we go about reforming the Justice Department, or is that even the best step to combat these behaviors?

A: Well, it is. The problem is that it's not going to happen. You would have to put some people in jail, and until you do that, nothing will happen. The problem is that the pharmaceutical industry and other health industries basically own Congress, and Congress essentially owns the Food and Drug Administration. Nothing is going to happen when there's that much money weighing in on the other side. One of the reasons that I enjoy talking, in a certain grim sense, about assisted dying is that there's no appreciable money at stake on either side. So when you talk about that, you're talking about something that people have some feeling about because almost everyone has seen someone die either a bad death or a good death -- usually the first. And so you can reason together, discuss the ethics and morals. When you're talking about the pharmaceutical industry or about single-payer health care, there is a lot of money against you. One of the things that we are unfortunately learning, and that I've learned over a long lifetime, is that you come up against big money, and it's like throwing grains of sand into the sea. You have to keep doing it, because it's the only thing you can do. But it really is distressing, and I think this is a good example. Pharmaceutical companies put drugs on the market that are more expensive than the drugs before them and are no better, as far as we know, and probably worse in certain cases. People usually don't have direct experience of it that they can analyze. They feel that drug companies are out there trying to discover new drugs and doing the best they can -- being innovative. But people accept the propaganda from these innovative companies and accept the notion that these companies have to charge outrageous prices to cover their research and development (R&D) costs.

Q: The me-too drugs are certainly a cause of concern, and treating R&D as a cash-cow isn't sustainable. I'm glad that you brought up big-money and the single-payer system. I know you're a fan of the single-payer system.

A: Yes.

Q: Do you believe that Obamacare – also known as the Affordable Care Act (ACA) – has led us in the wrong direction, or do you think it will eventually lead us to the single-payer system?

A: It continues us in the same direction because the two drivers of high costs and cost inflation were not touched by it. Those two drivers are, first of all, the profit-driven delivery system – the providers. Hospitals are either for-profit or behave as though they're for-profit. All of the for-profit imaging centers -- for example, outpatient facilities, clinics, the specialists and super specialists – get to perform as many high-cost procedures as they want; if they're, say, a cardiologist, they can make a couple of million dollars a year. Doctors vary in terms of their income; super specialists, in turn, perform high-tech procedures and get a lot of money for it. Providers are profit driven, and that's probably the biggest driver of increasing costs. They charge whatever the market will bear, and it will bear a lot with third-party payers. The second driver is the private insurance industry, and the hundreds of private insurance companies that compete by avoiding sick people and refusing claims. So those two things together have made the US health-care system extraordinarily expensive and inflationary compared with other countries.

So what did Obamacare do? It continued that. The private insurance industry got millions of new customers because people were required to enter a treacherous market and buy insurance. Obamacare did nothing about the profit-driven delivery system. That is still in place. Instead, Obamacare expanded coverage, but at a cost that simply cannot be afforded. These new patients who now have insurance cost a lot of money, so what you're seeing is the insurance slowly being hollowed out: the deductibles and co-payments are going up, so you have people who, yes, now have insurance, who weren't insured before, but can't afford to use it because the deductible is so high or it doesn't cover everything. So you're seeing more people with insurance, but the insurance is not as good. Sooner or later something is going to have to happen there.

Bud and I spent a lot of our breakfast table conversation centered on the direction that Obamacare would take the nation. We disagreed as to whether the policy was a step in the right direction or the wrong direction. He said, "Look, this is a step in the right direction. People will realize it. They will start to move toward a single-payer system. They will realize that it can't continue, but it's a step in the right direction. It was an attempt -- albeit an inadequate attempt -- and so there will be steps to make it adequate." I felt it was a step in the wrong direction because it gave the illusion of having reformed the system without any actual reform. When it fails, it becomes a third rail, just like after the Clintons tried to reform it. We can't touch this again, we tried it, it didn't work, we give up. I still feel that was the real danger. That was our

breakfast-table conversation.

CONCLUSION

Q: How feasible will it be to get Congress to step up? It seems like our representatives collectively are the biggest barriers to getting a single-payer system.

A: I don't think Congress will accept anything at all. So that's why, when people say it's unrealistic to promote a single-payer system because Congress won't pass it, I say, "So what will they pass?" Nothing. So you might as well argue for the things that you want and hope that Congress will change, that circumstances will change. I think it's a mistake to outsmart yourself by saying that we'll do what we can do. You have to see that with this Congress, particularly with the House, nothing will happen. You stake out what you think is the best position and hope that you will persuade enough people to eventually put pressure on Congress.

In my opinion, you need Medicare for all, and I would be willing to start one decade at a time, have the qualifying age drop from 65 to 55, and wait a few years, drop it another decade, until everybody is on Medicare for all. But it would have to also be in a non-profit delivery system. Europe does not have a for-profit delivery system. A few countries like Switzerland or the Netherlands have private insurance companies, but they're very different from what they are here. They are tightly regulated. The benefits are uniform, the prices are uniform. So you need a single-payer system in a non-profit delivery system. You argue that, you argue the merits, and you hope and pray that someday it will happen.

Q: Another important, and often controversial, part of Obamacare is the individual mandate -- the requirement that all Americans be enrolled in health insurance or otherwise pay an annual penalty. Do you believe that the individual mandate should be repealed out of the plan? Do you think the individual mandate was economically incentivizing?

A: Well, I don't like it. It's part of an impossible system, and I don't like it because it requires people to get insurance at whatever price the company charges. I think that's wrong.

Q: It's essentially playing into the hands of the insurance market if you're forcing the purchase of a particular good or commodity to get covered, and then inflating enrollment totals.

A: Yes, the insurance industry loves it. You have to pay what they charge you, and wonder if you have to pay a co-pay along with deductibles. It makes you powerless before them.

Q: Thank you for taking the time for this interview. It was lovely talking to you today.

A: You too. Good luck, Mike.

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[2] Relman, Arnold. "The New Medical-Industrial Complex." *The New England Journal of Medicine*. 1980; 303: 963-970, doi: 10.1056/NEJM198010233031703. <http://www.nejm.org/doi/full/10.1056/NEJM198010233031703>.

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[5] Ornstein, Charles. "New England Journal of Medicine increasingly targeted by critics." *Boston Globe*. April 5, 2016, <https://www.bostonglobe.com/metro/2016/04/05/new-england-journal-medicine-increasingly-targeted-critics/9H3JFKzTNJpCsOQqIUNXJP/story.html>.

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[7] United States District Court: Southern District of New York, <http://www.nysd.uscourts.gov/cases/show.php?db=special&id=478>.

[8] Kristof, Nicholas. "When Crime Pays: J&J's Drug Risperdal." *The New York Times*. September 17, 2015, <http://www.nytimes.com/2015/09/17/opinion/nicholas-kristof-when-crime-pays-jjs-drug-risperdal.html>.

[9] Ibid.

[10] Press Release. "Appeal of Conscience Foundation to Honor Alex Gorsky, Chief Executive Officer of Johnson & Johnson, with 2015 Appeal of Conscience Award." *Market Watch*. September 10, 2015, <http://www.marketwatch.com/story/appeal-of-conscience-foundation-to-honor-alex-gorsky-chief-executive-officer-of-johnson-johnson-with-2015-appeal-of-conscience-award-2015-09-10>.