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EDITORIAL

Scott's parabola and the rise of the medical–industrial complex

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In 2001, a British gynecologist J.W. Scott, M.D. published in the *British Medical Journal* a brief paper entitled "Scott's parabola: the rise and fall of a surgical technique" [20]. While sharing only a distant resemblance to the abstract mathematical definition of a parabola, the graphic representation does serve well to provide us with all too familiar surgical experiences within our profession. A procedure or therapy which shows great promise at the outset becoming the standard treatment after reports of encouraging results, only to fall into disuse as a result of negative outcome reports.

Artelon® arthroplasty, thermal shrinkage, Vioxx(r), metal-on-metal hip arthroplasty, and Infuse® bone grafting in the spine—all had come onto the "market" with enthusiastic reports only to fall from grace to unhappy outcomes, permanent disabilities, and malpractice litigation.

I will illustrate Scott's parabola with the evolution and demise of the dorsally applied π plate for the treatment of distal radius fractures. In the late 1980s, myself and three other hand surgeons working with the AO Foundation were brainstorming on newer concepts for internal fixation of the hand and wrist. I should preface this by stating that no royalties were ever involved although travel expenses, lodging, and meals were covered. We realized the tremendous opportunities that the locking screw technology offered and our initial small cohort series was published describing favorable results with limited complications [18]. Broad acceptance followed and the implant was widely used only to reveal numerous complications including extensor tendon rupture, screw breakage, and design and manufacturing flaws [10]. I should point out however that the volar component of the π plate system was very successful and continues to be used by surgeons throughout the world.

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The experience of the infuse bone grafting in the spine equally reflects Scott's concerns, although in this instance, unfavorable data were not accurately reported in initial reports [21].

> Artelon® artimplant AB, Vastra Frolunda, Sweden
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Why is Scott's message so meaningful? I would like to explain this by (a) defining existing problems inherent in our scientific studies, (b) bring into focus the medical–industrial complex and its impact on health care and, (c) look at how we might establish a more responsible methodology in our innovation of new procedures or technologies and its relationships with industry.

Musculoskeletal research and publications currently tend to reward positive results especially those that appear to improve the surgeon's ability to treat the clinical problem. For a number of reasons, there is little motivation to either perform negative studies or even studies that duplicate prior published data. Douglas Jackson, writing in an editorial in *Orthopedics Today*, observed that reproducibility of published work is only occasionally challenged by knowledgeable scientists and clinicians who work in the same field or by industry before proceeding with product development and introduction [7]. He noted that this is in contrast to the experience of most venture capitalists who will be more inclined to reproduce results by independent observers before committing to early funding. It is striking that "positive" trials and "negative" trials take the same amount of time to conduct; however, negative trials take 2 to 4 years longer to published during which time patients may receive ineffective or harmful treatment.

Dr. John Ioannidis, considered one of the world's foremost experts on the credibility of medical research, has shown in many different ways that much of what biomedical researchers conclude in published studies is misleading,

exaggerated, and at times wrong [3]. Ioannidis first realized that such problems existed as a young medical researcher at Harvard University in the early 1990s. A new "evidence-based medicine" movement was just generating enthusiasm and, having been a mathematics prodigy in high school, he saw the chance to combine math and medicine by applying rigorous statistical analysis to the field.

In 2005, in a paper in the online journal *PLoS Medicine*, Ioannidis laid out detailed mathematical proof evaluated studies in different fields of medical research that 80 % of non-randomized studies turn out to be in error as do 25 % of supposedly "gold standard" randomized trials and as much as 10 % of the "platinum standard" large randomized clinical trials [5]. He found even in the randomized controlled trials that "at every step in the process room to distort results, make a stronger claim, or select what is to be concluded." These included (a) what questions researches asked, (b) how they set up the study, (c) which patients were invited, (d) which measurements used, (e) how data analyzed, (f) how results presented, and (g) how studies came to be published.

In a second article in *Journal of the American Medical Association* in 2005, he studied 49 of the most highly regarded research findings in medicine over the past 13 years [6]. Of the 49 articles, 45 claimed effective treatments. Thirty-four of these had been retested and 14 or 41 % had been shown to be wrong or significantly exaggerated.

In an article by DH Freedman entitled "Lies, Damned Lies, and Medical Science," Ioannidis is noted to suggest that much of the wrongness problem could be solved if the world stopped expecting scientists to be right. However, as long as careers remain contingent on producing a stream of research that is dressed up to seem more right than it truly is, scientists will keep delivering exactly that. "Science is a noble endeavor but also a low-yield endeavor. I am not sure that more than a very small percentage of medical research is ever likely to lead to major improvements in clinical outcome and quality of life. We should be very comfortable with that fact" [3].

While innovation and technology, necessities of the surgeon's armamentarium, produce most of the substantial advances in surgery, it is reality that most of the surgical device technology originates in industry research and development sections rather than from grant-supported research in academic clinical and basic science labs.

We must now explore this relationship and what has been coined by some as the "medical–industrial complex." Given the three trillion dollar health care industry, it is not surprising that it is one of the biggest and fastest growing businesses in the USA [14]. The term medical–industrial complex, first introduced by Barbara Ehrenreich in her book "The American Health Enterprise: power, profits, and politics" [1], is a direct spin off from the theme of President Dwight D. Eisenhower's farewell address [2]. Eisenhower warned the nation of the risks of an emerging military–industrial complex and the growing dependence of universities and research laboratories for federal funds which had the potential to compromise researchers in their search for truth as well as reduce the "scholar" to an "obedient servant."

What Ehrenreich identified as the medical–industrial complex is the multi-billion dollar interaction of enterprises including physicians, allied health personnel, hospitals, nursing homes, insurance companies, and multiple industries among others.

Paul Starr, who became a leading figure in the Clinton health care reform brain trust, published in 1982 a landmark study of the social and economic development of medicine in America [22]. His final chapter entitled "The Coming of the Corporation" describes the new corporate transformation of the US health care system and its growing threat to the sovereignty of the physician.

Arnold Relman, M.D., former editor of the *New England Journal of Medicine*, was the first mainstream physician to write about the medical–industrial complex observing that the corporatization of medicine represented a challenge to physicians' authority, autonomy, and even legitimacy particularly for the doctors who become health care industry owners or with financial stake in the industry [16]. Yet, what was relevant about his concerns was that he was not concentrating on the companies that manufacture pharmaceuticals or medical equipment as they have been around for a long time and no one truly challenges their social usefulness. Rather, when focusing on the medical profession, he argued that if physicians are to represent their patients' interests in the new medical marketplace, they should have no economic conflict of interest [17].

The evolution of the medical–industrial relationships can be most clearly reflected in the biotechnology world at Stanford University. For a number of years, little relationships existed between the corporate world until the 1970s when Dr Stanley Cohen working with Dr Herbert Boyer at UCSF invented a technique that allowed mass production of human proteins and, in effect, gave birth to the new biotechnology industry. Yet, Dr Paul Berg at Stanford, a Nobel laureate, objected to Stanford following this path only to see Stanford reap a financial windfall. Berg voiced concerns regarding the future dangers of these associations [8]. Ultimately, Stanford Medical School established a ten-member conflict of interest board to oversee industrial relationships. Yet, critics still feel that disclosure alone is not the solution and some aspects of the medical–industrial relationships should not be allowed [9].

Dr. Sidney Levitsky, a cardiothoracic surgeon at Beth Israel Deaconess Medical Center, also has been vocal in similar concerns yet has clearly identified the reality facing many academic centers "No Margin No Mission" [13].

It is ironic that we continuously hear of fraud and waste in our system from our politicians with threats from the

office of the Inspector General of imminent prosecution. Dean Kaman, a noted entrepreneur, suggested "if you listen to what a lot of our political leaders say, they believe that industry is a bunch of people that get together every morning and say 'what new innovation can we make that is more expensive, less effective, and maybe kill babies just gratuitously'" (http://www.mddionline.com/article/election/Are-Politicians-The-Biggest-Enemy-To-Medtech Innovation).

It is not surprising that those profiting in the medical–industrial complex such as pharmaceutical companies and to some degree medical device companies lobbied congress during the health care debate to keep them in the shadows. Physicians, who account for at best 20 % of the health care expenditures, are portrayed as overpaid and motivated primarily by volume in the current payment systems.

If we return to President Eisenhower's admonitions and place them in the context of the medical industry, we can now appreciate his concerns: "we must guard against the acquisition of unwarranted influence, whether sought or unsought, by the (sic) 'medical–industrial complex.'" Should we be surprised that the department of justice fined five major orthopedic device companies 311 million dollars imposing mandatory compliance measures? [24]. The Sunshine Act as part of the new health care reform bill further placed restrictions on gifts to surgeons and has stimulated greater scrutiny of conflicts of interest. Some have cynically suggested that, in reality, this has become a boondoggle to compliance bureaucrats and legions of lawyers.

Government interventions in health care regulations including drugs and devices are by no means modern developments. Henry III of England, in 1266, established the Assize of Bread and Ale law regulating the weight and purity of bread and the volume of ale [19]. The term "Baker's Dozen" originated from this law. In 1813, the Vaccine Control Act was created to guard against adulterated smallpox vaccine. In 1902, the Biologic Control Act was passed in response to the death of 13 children in St. Louis and 9 children in Camden, New Jersey, due to improper vaccine preparation. A horse named Jim had produced diphtheria anti-toxin serum contaminated with tetanus. In 1906, the Pure Food and Drug Act, considered the founding date of the FDA, was created due to exposed corruption in the meat packing industry. This was expanded in 1938 by the Federal Food and Cosmetic Act influenced by the death of more than 100 patients due to a sulfanilamide medication dissolved in diethylene glycol. In 1962, the Kefauver–Harris Amendment was passed in response to the thalidomide disaster, and for the first time, a drug must be proven to be both safe and effective (http://www.fda.gov/centennial/history.html).

The story of the Dalkon Shield intrauterine birth control device represents very dramatically the wide acceptance of a medical device based upon faulty science and industry greed [12]. The device was invented by Hugh J. Davis, M.D., a professor of gynecology at the Johns Hopkins Hospital. He sold the rights to A.H. Robbins in 1971 for $750,000 and 10 % of sales. The device was promoted based upon a single study by Davis which claimed a 1.1 % failure rate when the actual rate was 5.5 %. The flawed design, used by 2.8 million women, was responsible for birth defects, sepsis, and death and 300,000 lawsuits. Billions were involved with legal fees and settlements leading to bankruptcy for A.H. Robbins who knew almost from the beginning of problems and ultimately withheld and destroyed information. This prompted the Congress to enact the Medical Device Amendment Act of 1976 and, now for the first time, the FDA regulated medical devices (http://www.fda.gov/CombinationProducts/default.htm).

With the defined process of regulatory control provided by the 1976 Act, what explanations then exist for the fact that we still experience the realities identified in Scott's parabola with many new technologies? Part of this has to do with the FDA classification of medical devices and the differing device approval process. Class I medical devices exempt 95 % of the time from regulation. Class II devices require what is known as premarket notification, the 510(K), allowing for a less expensive and more expedited review, while the Class III critical devices need premarket PMA requiring an IDE and IRB study. Yet, we see now more and more criticism of the approved process and the Institute of Medicine Report in July 2011 concluded that "the 510(K) process lacks the legal basis to be a reliable premarket screen of the safety and effectiveness of moderate-risk devices and, furthermore, that it cannot be transformed into one" (www.iom.eduReports2011/Medical-Devices-and-The-Public Health).

Perhaps we can look at our relationships with industry and ourselves in alternative ways.

J.D. Kleinke writing in the *Wall Street Journal* observed:

"Many physicians are understandably threatened by this watershed in the history of medicine, this challenge to 2500 years of clinical hegemony. From unquestioned GOD to accountable production workers is a long way to fall in a few short years" [11].

Has the pendulum swung too far? Is our rush to adopt new technologies truly associated with conflicts? Thomas Stossel, M.D., Professor of Medicine at Harvard Medical School, is not so certain. He has argued that it is really a small minority of voices impeding medical and scientific progress with their concerns about potential conflicts of interest and decrying the beneficial relationships between industry and medicine (http://www.policymed.com/2011/11thomas-stossel-addressed-american-college-of surgeon). He would like to see abuses involving financial conflicts of interest treated more like cases of scientific misconduct. Rather than forcing everyone to abide by prohibitive rules, administrations should focus on those who misbehave.

"Disclosure policies are no longer a way to honor the sponsor of a study, but rather they have been turned into a

type of confession. In practice, disclosures are being used by the media to embarrass people. We have gone from bad to worse. We have immense regulatory issues and massive confessions where we disclose our relationships to industry and these are used to initiate a variety of inhibitions of freedom of speech, freedom of association, and rewards for excellence"

He suggests that the reasons given for these restrictions are "that those in industry allegedly live in a separate moral universe than medicine…the idea is that those who work for industry are obligated to lie, cheat, and steal for profit and for your investors and those who make such assertions have launched the conflict of interest mania."

He also points out that medical care is incomparably better now than when he received his M.D. degree in 1967 due primarily to the availability of products developed by industry in collaboration with physicians and to industry's commitment to teach physicians how to use them [23].

He notes that the 2009 Institute of Medicine report on conflict of interest was unable to find evidence that relationships adversely affect what really counts—patient outcomes [4]. Who really doesn't care? The consumers as few patients have time, interest, or competence to interpret disclosures. Most survey data indicate that patients have few concerns about physician–industry relationships.

Should not the balance scale be tipped more towards our own ethical behavior and scientific integrity rather than compliance rules, disclosures, and regulations.

When we think of the harm some of our new technologies have caused our patients, it is necessary to think of our moral obligations in patient care. Economist Paul Krugman described moral hazard as "any situation in which one person makes the decision about how much risk to take, while someone else bears the cost if things go badly" (Krugman.blogs.nytimes.com/2008/05/09/avoiding-moral-hazards).

In the end, the words of Francis Weld Peabody in Boston writing in 1927 in JAMA should hold true:

"One of the essential qualities of the clinician is interest in humanity for the secret of the care of the patient is in the caring of the patient" [15].

Conflict of interest The authors declare that they have no conflict of interest. There is no violation of human and animal rights. There is no informed consent as no human subjects are involved

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