

The impact of greed on academic medicine and patient care

John V Frangioni

To what extent is the increasing emphasis on profit generation at US academic institutions shackling intellectual freedom and compromising healthcare?

"Greed is good." —Gordon Gekko from Oliver Stone's film Wall Street

Gordon Gekko's rapacious catchphrase reminds us that capitalism has no boundaries. Although free markets are presently the best way to effectively and efficiently allocate goods and services developed by our society, they are ultimately driven by 'supply and demand', which has, at its core, the leveraging of human need and desire. So, what happens when the 'need' is human health and therefore life itself? Should all decisions in the pipeline, from discovery to delivery of a new device, diagnostic product or therapy, be based on maximizing profit when, in fact, US taxpayers have directly or indirectly funded nearly every major discovery in medicine over the past 40 years?

The present system for the delivery of improved, cost-effective healthcare in the United States is not working, in large part because an otherwise functional system has been co-opted for monetary gain. Although entire books are devoted to the interplay between academia and industry¹, my aim here is to explore the sometimes subtle, sometimes obvious effects of greed on academic medicine and, ultimately, patient care.

The role of academic medical centers

Historically, academic medical centers (AMCs) were places where the next generation of physicians was being trained (with the help of US government subsidies; **Fig. 1**) while fundamen-

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Greed pervades US healthcare to the extent that we are now in need of a new prescription for biomedical research.

tal research into the prevention, mechanism and treatment of human disease was being conducted (again, with the help of US government subsidies). They were viewed, and rightly so, as crucial centers of innovation where monetary profit was secondary to the societal profit of improving patient care. Indeed, they were also the places where the 'safety net' that barely holds together the US healthcare system was spread the widest².

US citizens and taxpayers expect that AMCs maintain their hard-earned status of independence from external forces and place the public good higher than any other motivation. If not, then why are we subsidizing them? Sadly, however, over the past decade, AMCs increasingly have treated their research (and clinical) enter-

prises as potential profit centers, with behavior at the personal and institutional level that I would label greed. Such greed undermines the mission of AMCs and, therefore, their very existence.

The facade of tax-exempt status now shielding many of these multi-billion-dollar corporations is wearing thin. Academia must ask itself a simple question: "Is the singular goal of AMCs to improve human health without placing monetary gain higher than any other principle?" If the answer is yes, please continue reading. If this answer is no, then pronounce dead another US institution of great value to the average US citizen.

The protean incarnations of greed

The wonderful thing about greed, and why it permeates virtually every aspect of the US healthcare system, is that one can rarely find two well informed, intelligent people who can agree on whether it exists in any given situation. Is an assistant professor at a medical school who starts a company based on his or her research, with the goal of sending his or her children to a private college, greedy or just entrepreneurial? Is a private AMC that sells a discovery made by one of its researchers to the highest corporate bidder, rather than the partner best suited or best qualified to bring it to market, fulfilling the mandate of the Bayh-Dole Act of 1980 or engaging in unsavory practices? Is a company that prices a life-saving treatment that originated in academia as high as the market will bear exercising good capitalism or engaging in profiteering? These are not trivial questions, but rather ones that speak to the public's trust and confidence in AMCs and how AMCs interact with the private sector. The present relationship among taxpayers, AMCs, for-profit companies

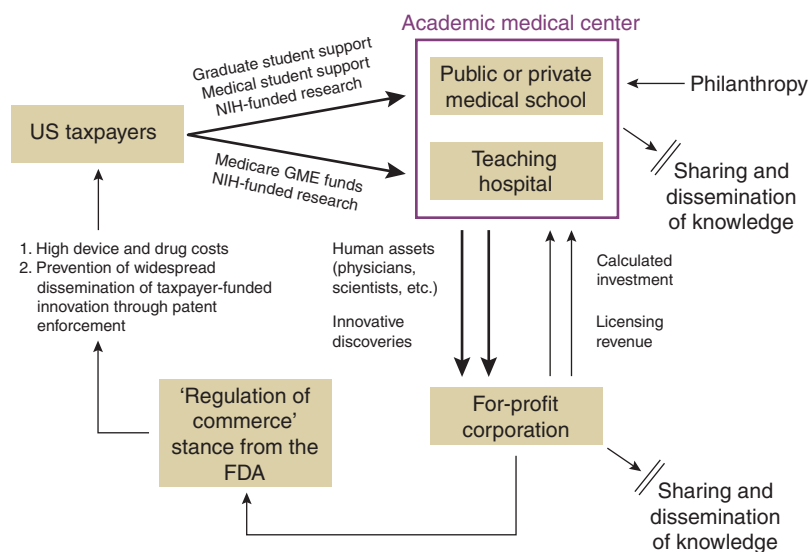


Figure 1 The present public-private system for funding and disseminating knowledge. Arrows denote flow from one organization to another of money, human assets or both. GME, graduate medical education.

and regulatory agencies is complex (Fig. 1), but it could be construed by some as a thinly veiled system of corporate welfare.

Most patients, and their families, would be discouraged to learn how decisions are now made to bring new devices, diagnostics and therapies to the clinic. My underlying thesis is that greed clouds judgment, impedes progress and unnecessarily benefits the few at the expense of the many.

Personal greed. The access of individual researchers to the money made from their inventions varies greatly among AMCs. At one extreme, rarely seen nowadays, the individual researcher would be free to license the technology to a for-profit company as he or she sees fit, with no true reporting obligation or impediment to continuing work in the field within their AMC laboratory (or clinic). At the other extreme, some AMCs have adopted the policy that individual researchers can only continue to work on technology they invent if they forego all equity in any start-up company or joint business venture arising from it, and receive only an indirect licensing royalty, which is negotiated and administered by an independent technology-licensing office.

In my opinion, there are several reasons why the latter policy is probably the best for the individual researcher, the institution and the public. No matter how one might try, one's judgment is impaired when money is at stake. Human clinical research, in particular, cannot afford such impaired judgment. Nor is it in the interest of an individual researcher to let money-motivated decisions risk her or his academic reputation. Most inventions do not make much

money anyway (see below). And indirect royalties shield the investigator, and to a lesser extent the institution, from the suggestion of impropriety. Furthermore, there is a clear option for individual researchers who rank making money higher than continuing their research: they can simply leave academia.

The counterargument is that without the inventor acting as a 'proponent' of a new technology, it will not move forward as a product, and therefore the taxpayer will be denied its benefit. Hogwash. In a capitalist system, if the technology is robust and serves a large and lucrative market, investors will find ways to commercialize it, with or without the assistance of the inventor.

Institutional greed. Institutional greed can be traced back to Gatorade, invented at University of Florida (Miami, Florida, USA); paclitaxel (Taxol), invented at Florida State University (Tallahassee, Florida, USA); cisplatin (Platinol), invented at Michigan State University (East Lansing, Michigan, USA); and DNA transformation, invented at Columbia University (New York)³. AMCs took notice as these four institutions collectively made billions of dollars on these patents over the past three decades. Suddenly, research was viewed as a potential cash cow and, upon passage of the Bayh-Dole Act, virtually every AMC established a technology licensing office.

With such offices came stringent policies on the disclosure of potentially patentable inventions and their communication in public forums, such as papers and talks. In very little time, institutions adopted the same model for intellectual property (IP) protection as for-

profit companies. However, a careful analysis of patent revenues by AMCs suggests that lucrative patents are truly exceptions. The norm is a confusing and time-consuming system of IP protection that costs many institutions more money than it generates³. As the director of a technology licensing office at a major AMC likes to quip, "If you want me to make money for the institution, let me run the parking garage."

More importantly, the present similarity in behavior of AMCs and for-profit companies is extremely damaging. First, it places AMCs in conflict with the US taxpayer because AMCs are permitted to negotiate the highest possible licensing fee, which will eventually be passed on to the consumer. Second, it impedes scientific progress because of restrictions imposed on the free dissemination of information and materials among academic investigators, and may even hold up publication of results until IP protection is in place (Fig. 1). Third, it makes AMCs potential targets for patent infringement suits from for-profit companies⁴ because the line between academic mission and profit has been so blurred. Fourth, when AMCs engage in the reverse—high-profile IP lawsuits against for-profit companies—the public might be confused because most believe that the AMCs aren't 'in business.' Fifth, it encourages AMCs to focus resources on inventions that could potentially serve a large market size and therefore reap higher royalties, instead of those inventions that might benefit only a small number of patients but do so effectively. In either case, IP protection costs are high. And, finally, when an AMC fosters an environment centered on money instead of one centered on the public good, philanthropic giving will be put at risk.

Corporate greed. What happens to IP that is finally licensed by a for-profit company from an AMC? The answer is: whatever the company wants. Despite claw-back (that is, 'march-in') provisions in the Bayh-Dole Act and in most AMC-granted licenses to prevent 'stalling', I have been able to find few examples of the federal government, or an AMC, invoking such provisions. Doing so, of course, might jeopardize the next deal with a potential licensee. Stalling has many common causes—including poor company management, a lack of internal funding, pressure from investors for short-term rather than long-term gains (especially prevalent in start-up companies) and elimination of competition (sequestering IP within a company to prevent others from working on it)—but in the final analysis, it is safe to say that all decisions regarding the development of licensed, US taxpayer-funded innovations are based on maximizing profit.

Two sobering examples of how for-profit companies behave in the context of AMCs and patient care come to mind. The first relates to the efficiency with which products progress through development; the second, to the ability of the academic system to educate and retain the best minds.

I know of a company that has an innovative treatment for stroke that seems effective when tested in animal models. This discovery arose indirectly from federally funded studies at an AMC. When asked why the treatment hadn't moved from discovery to human trials, the answer from the company was that a strong business case couldn't be made for the relatively small stroke market, especially in the context of regulatory approval costs. Thus, the technology is now sitting on the shelf, unused. Maybe it would have worked in patients, and maybe it wouldn't have, but the thought of patients being denied relief from the devastation of stroke is unethical. However, there is no legal or other remedy to this situation, and the company's shareholders would argue that it made a good business decision. Giving the IP back to the AMC, or the AMC 'buying back' the IP from the company, simply doesn't happen, for financial reasons.

The other point about corporate greed relates to education and retention of the best minds. I recently attended a meeting where a pharmaceutical industry representative was talking about recruiting top clinical researchers away from AMCs. Two comments, in particular, were telling. First, the company rep claimed, "I can 'out-recruit' you [AMCs] any day of the week." True, in fact, but recall (from Fig. 1) that US taxpayers pay for the training of most graduate students and medical residents in the United States through Medicare Graduate Medical Education funds and National Institutes of Health (NIH; Bethesda, Maryland) training grants. His second comment revealed the stark reality of the private sector: "If you're looking for industry to help pay for the training of clinical scientists, you might have fewer friends than you think." True, again, because the only thing that matters to a for-profit company, by definition, is using resources to maximize profit. And, because US taxpayers already pay for the education and training of industry's best people and industry only needs to pay a small premium to displace these individuals from academia, this makes great business sense.

Finally, large pharmaceutical and medical device companies have often abandoned their internal R&D activities in favor of 'mining' small startups that initially license taxpayer-funded innovations from AMCs. Some of these larger companies now function as clearinghouses that

use their regulatory experience to bring a drug or device to market and their branding and merchandizing experience to maximize cost to the healthcare system, and thus to maximize their own profit. Again, it's good business, but bad news for the US taxpayer.

Thus, AMCs provide for-profit companies with many of the innovations they need to fill their product pipeline and most of the human assets they need to commercialize these innovations. In return, US taxpayers pay the highest possible prices for new technology, pay for the training of individuals who populate for-profit companies, and are denied possible new treatments because of profit calculations. Taxpayers who hold shares in these companies might like the dividends this system creates, but for most of us, it's a bad deal.

Possible solutions

As is evident from the above discussion, no single entity is culpable for all the faults of the present system, and the impact of greed could be extended further to include certain relationships among physicians, hospitals and insurance companies. Unfortunately, such a distribution of fault makes correcting the problem even more difficult.

AMCs have a fiduciary responsibility to the US taxpayer, who funds some of the finest graduate medical education, graduate school training and medical research in the world. AMCs are also institutions that, historically, put the improvement of public health higher than any other priority, including money. To maintain their legitimacy, the goal of AMCs should be to return to the timely dissemination of new knowledge and technology to the public in a cost-effective manner.

So, how can AMCs rescue themselves from the slippery slope they are now sliding down? And how can the present dysfunctional system of moving AMC innovations from the discovery phase to patient care morph into one that benefits all parties, including for-profit companies? I would argue that reform is possible, but only in the unlikely scenario that the following three events occur in parallel: fundamental changes at AMCs, legislative action and new business models.

Changes at AMCs. One key goal for AMCs should be to focus on dissemination of technology rather than protection of IP, because (i) many new inventions are ahead of their time, (ii) still others have little commercial value but great scientific value and (iii) IP filing and enforcement costs are extraordinarily high. For reference, in fiscal year 2006, 4,963 licenses were signed at AMCs from a total of 18,874 new invention disclosures (27%)⁵. Under exist-

ing policies, the remaining 73% of IP is 'potentially' licensable and therefore unavailable for the public good. In my own area of imaging, for example, there is scant evidence that our present system of technology dissemination works well. Positron emission tomography took more than 50 years from its invention to reach the clinic, and computed tomography and magnetic resonance imaging more than 20 years each. Some of this lag was technical, but much more was based on IP and licensing issues, profit calculations and regulatory burdens. Similarly, in the diagnostic arena, the number of new agents approved for clinical use over the past half decade is dismally low⁶.

For all of these reasons, AMCs should abandon their current IP stance and create an organization for open-source dissemination of most technology. Examples already exist, such as the nonprofit organizations CAMBIA (<http://www.cambia.org>, an open-access resource for assisting developing countries with technology sharing) and Addgene (<http://www.addgene.org>, a resource for reagent distribution), although neither organization has solved the major issue of 'freedom to practice'. During such a shift in focus, technology transfer offices would be converted into technology dissemination offices. Instead of how many deals the office executes, the metric for success would be how many other AMCs (and for-profit companies) are using taxpayer-funded innovations to promote human health.

A second key goal for AMCs should be that, when they do decide to protect and license IP, they should be much more stringent and selective about it. Most AMCs still crave Gatorade-like royalties. For some technologies, and at least for the interim, IP protection and exclusive licensing might be the best way to benefit the taxpayer. However, in light of a recent US Supreme Court decision⁷, AMCs should be extremely selective with what they submit for IP protection, and they should focus more on open-source dissemination.

A third goal should be to stop tolerating small 'effect sizes' when making IP-protection decisions. Diagnostics, therapies and devices that don't make a substantial improvement in human disease should stay in the research setting until they do, and interim advances should be reported and shared freely. To make these judgment calls on which IP to patent-protect and license, it would be critical for AMCs to take their products to the proof-of-principle stage in humans, where it becomes much clearer whether a technology will affect healthcare—hence the need for more translational research.

A fourth, related goal needs to be a paradigm shift away from the present reliance on for-profit companies to move new technology from

'bench to bedside'. AMCs must invest heavily in creating infrastructures that support their own first-in-human trials. For example, virtually all current good manufacturing practice syntheses can now be contracted out at reasonable costs, and regulatory consultants abound. For a relatively modest investment, AMCs around the country would be able to tap into their vast clinical network of patients in need to test new devices and agents safely, cost effectively and cost efficiently. By doing so, they would be fulfilling their primary mandate and, in the process, could provide either for-profit companies or nonprofit entities (see below) with product leads having a greatly mitigated risk.

A fifth goal, which is key to reaffirming the trust of the public in their academic institutions and diminishing the biases that are affecting the free flow of information and scientific progress, is to create policies for avoiding conflict of interest. Recent headlines of researchers with financial interests in clinical studies that they conducted or in companies for which they were consulting underscore the need for enforceable policies at AMCs to eliminate these practices. At present, such policies are neither comprehensive nor consistent⁸. More importantly, AMCs need to investigate why researchers are willing to take such risks. It could be as simple as greed, but it is as likely a cry for more competitive salaries, more recognition, support for their program or some other relatively simple fix that is less costly and damaging than negative news headlines. As an aside, adopting some or all of these policies would also add legitimacy and imperative to philanthropic giving, which for many AMCs could easily surpass licensing royalties.

Legislative action. The US government should encourage AMCs to place a greater focus on translational work and on technology dissemination and sharing in four ways: modifying the current regulatory system, modifying the current IP and patenting system, boosting funds for translational research and protecting AMCs from potentially harmful litigation.

Our current system of regulatory approval and monitoring is too expensive, time consuming and slow—facts that are readily acknowledged by the US Food and Drug Administration (FDA; Rockville, Maryland)⁹. In my opinion, though, the fundamental problem is not with the agency and the resources at its disposal, but with the technology and products presented to it. AMCs and industry currently overemphasize incremental improvements instead of quantum improvements. And drugs and devices with small effect sizes both cost a lot to approve and sequester considerable FDA time and resources, with relatively little benefit for patient care.

Nevertheless, there are some possible FDA reforms that could improve the efficiency of translation considerably. And, although it is likely that legislative action would be required for their implementation, they could be designed to maintain patient safety as a paramount goal. First, require the FDA to work with the NIH institutes to assist with the approval and dissemination of government-funded innovations in a cost-effective manner. There is at present far too little communication, interaction and understanding between the two agencies. Second, create an office to assist AMCs and nonprofit entities with the design and execution of first-in-human trials, including an off-record concierge service where regulatory questions can be answered without the fear of adding more requirements to a future application. Third, eliminate or reduce user fees for New Drug Applications, which are now so high that AMCs cannot afford them. Fourth, require that a new device or drug be 'better than' an existing one before approval is granted, rather than the present standard that makes equivalence acceptable. Fifth, issue rules rather than 'guidelines,' which are often vague, difficult to interpret and add excess cost to the process because of second-guessing. In the long run, these reforms help industry as much as AMCs because the net result is more first-in-human testing and the elimination of devices and drugs with small effect sizes from the marketplace.

In terms of modernizing technology transfer, the US Bayh-Dole Act has been a great stimulus for the commercialization of government-funded innovations¹⁰, but it is also largely responsible for the situation we are now in. In my view, the Act needs to be rewritten to eliminate the requirement to file patents and instead focus AMCs on dissemination of technology to the US taxpayer: the metric for success should be dissemination, not commercialization. Claw-back provisions need to be strengthened and open-source dissemination needs to be encouraged and supported. There is also a need for clarification within the Act that the goal is to return technology to the taxpayer who paid for it, regardless of whether this return is in the form of low-cost, nonprofit dissemination or high-cost, for-profit dissemination.

For US patents, some argue for increasing the enforcement period, and thus monopoly, for new drugs and devices¹¹. This is difficult to justify, though, given the expense to the healthcare system, emphasis on marketing over R&D by many big pharmaceutical and generic companies, and the fact that most patented agents have a relatively modest effect size. I would argue for a greatly reduced period of exclusivity, which would be justified by focusing on large effect sizes, which in turn would

reduce approval costs and approval times. It should also be noted that in a truly 'free' market, companies would compete for market size by providing better products at a better price, not excluding others through patents. Supposed patent-reform legislation now pending in Congress¹² does little to address the fundamental problems that exist. It may be time to readdress the concept of anticommons¹³ and restrictive licensing policies, as well as to think about instituting anticompetition laws that prevent companies from capturing large areas of IP space and holding innovation hostage by preventing freedom to practice.

Of course, the move to more translational work will require a doubling or tripling of the current NIH budget; the present budget is inadequate to assist with the clinical translation of new innovations. Because of this, and because of the NIH's relatively unproductive relationship with FDA, most innovations never benefit US taxpayers. Any increase in NIH funding, though, needs to be earmarked specifically for the clinical translation, regulatory approval and safe and inexpensive dissemination of new technology (see 'new business models' section below), especially when such technology is not patent protected. These extra funds should also be used to help increase the number of clinical researchers and to retain them at AMCs. Given the size of our physician pool in the US (~800,000), it is a sad statement that <2% (~15,000) are engaged in patient-focused research¹⁴. Without such physician-scientists, clinical translation of government-funded, AMC-developed technology will not be possible.

Last, a clear need exists for litigation limits for government-funded research carried out at AMCs. The fear of litigation is a chief reason why many AMCs have not stepped up clinical translation efforts. This problem could be eliminated by legislative action that limited liability for researchers and nonprofit AMCs engaged in the clinical translation of innovations funded by the federal government. Indeed, if regulatory requirements for the research are met, all parties act in good faith, and patients are well informed about the inherent risks of new devices and agents, there is no need for litigation. As a *quid pro quo*, government funding released to AMCs would depend on adherence to these principles.

New business models. Being based on greed, the present system of clinical translation is focused on multiple 'handoffs' between investigator, AMC and industry, with the goal of each one being monetary gain. It also focuses far too little on agents and devices with a large effect size, and it attempts to license technology far too early in the development process. This system cannot be

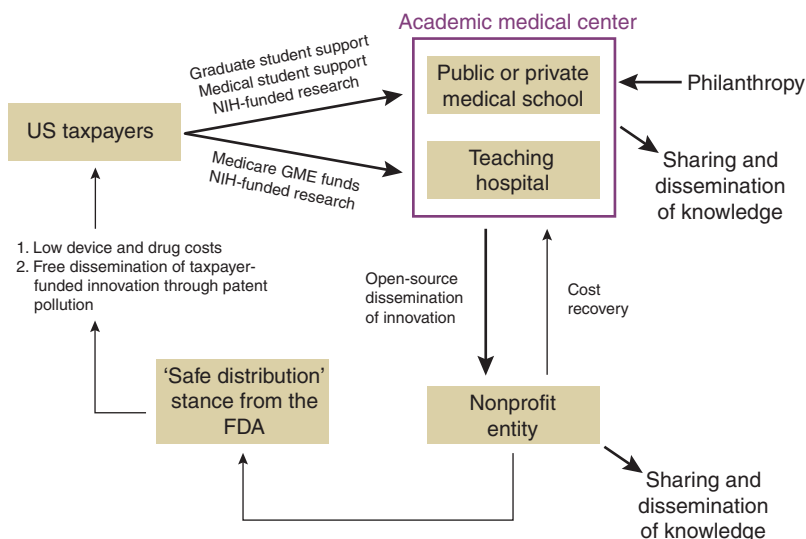


Figure 2 Potential model of AMC-nonprofit primacy for the development and dissemination of certain US taxpayer-funded innovations for small market sizes. 'Patent pollution' refers to the public disclosure of new ideas and inventions such that subsequent patenting is precluded.

sustained as we enter the 'molecular revolution', which promises patient-specific diagnostics and therapeutics for most diseases. Market size for any one agent will be quite limited, and effective diagnosis or therapy will likely require patient-specific 'cocktails' of agents selected from a larger menu. Developing new business models that address such personalized treatment will be a huge challenge, but here, too, open source IP may be a key part of the equation.

Along with open-source IP, strategic public-private partnering between industry and AMCs capable of performing first-in-human trials could greatly accelerate the commercialization of new devices and drugs while reducing costs. AMCs already have the patients in need, as well as the clinicians who understand the disease. If AMCs are willing to change their current practice of charging unreasonable per-patient fees to trial sponsors, and instead work collaboratively with for-profit or nonprofit entities interested in the sale or distribution, respectively, of a new device or agent, trials could be conducted faster and cheaper, without compromising patient safety.

Public-private partnering is an area that has already had some notable successes, particularly in the area of neglected diseases, and could be expanded. A recent example is the Institute for OneWorld Health (<http://www.oneworldhealth.org/>). Another example that extends this concept to diseases with large markets (with an initial focus on cancer) is GlobalCures (<http://www.global-cures.org/>), a nonprofit medical research organization that aims to test the clinical efficacy of therapies that have scientific merit but for which financial reward might be

uncertain. Drugs off patent, those nearing the end of their patent life (in a particular indication) and substances that were never patented could provide the input for these trials.

Finally, under the current system of device and drug development, success is measured in dollars. However, for nonprofit patient advocacy groups and disease-specific foundations, the metric for success is actually concordant with that of the US taxpayer, namely, 'save my loved one'. If we truly want to make government-funded innovations available to the healthcare system at the lowest possible cost, for-profit commercialization as it is implemented now probably is not the answer. As a temporizing alternative, imagine that AMCs focused on drugs and devices with large effect sizes and that legislative action reduced regulatory costs and partnered the FDA with the NIH to speed clinical translation. Nonprofit entities might then be positioned to manage the safe and efficient dissemination of certain technology, especially when market sizes are small (Fig. 2). Such dissemination would be performed with recovery of distribution costs, so the entity (and AMC) would remain sustainable, but without profit and without advertising, marketing and R&D costs. I suspect that the brainpower needed to make such nonprofit entities viable is available; there are enough brilliant businesspeople in the US who have watched loved ones die and wondered why new treatments weren't available.

Conclusions

The snail-like improvements in the treatment of human disease is discordant with the

amount of money being spent by US taxpayers, and has as its root the relatively modest improvements that most new technology really provides to a particular field. Indeed, the system that has evolved to return US taxpayer-funded innovations back to them as affordable treatments is a contradictory mixture of corporate welfare (taxpayer-funded innovations and human assets) and gouging of corporations (high licensing fees and astronomical regulatory costs) that encourages, and even necessitates, greed at the personal, institutional and corporate level. And, in the context of academic medicine and patient care, greed is not good.

No one has yet solved the problems of heart disease, cancer or diabetes. When these diseases are cured, this success will likely be traceable back to AMCs and government-sponsored research. Will we be selling these improvements in human health to the highest bidder, or will US taxpayers receive a fair return on their investment in the form of better, more affordable healthcare? The overused phrase 'bench to bedside' will remain a myth until AMCs return to their roots and work with government and nonprofit entities to traverse the 'critical path' from discovery to technology dissemination, with effect size, rather than monetary gain, as the primary motivator.

ACKNOWLEDGMENTS

I thank M.L. Zeidel, R.E. Lenkinski, J.S. Felsch, M.D. Chalek, P.F. Levy, V. Sukhatme, J.S. Flier and M. Rosenberg for many discussions, B.L. Clough and A. Gugelmann for editing, and E. Trabucchi for administrative assistance. I especially thank C.T. Lemon for his thoughtful analysis of capitalism and S.J. Nowak III for his thoughts on profit.

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