- Commentary -

Physicians Owned Distributorships Are They The Same As Physicians Dispensing Drugs?

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Worth mentioning that modern trends in “**The Business of Medicine**,” although carefully crafted by modern men to stay within legal boundaries, when viewed by many often morally and ethically test “tolerances” of same. This applies to the blunt consideration as to whether the modern orthoped who hopefully still wishes to behave appropriately as judged by his peers and colleagues, really should risk his reputation by getting involved in ownership of an implant distributorship where many critics may doubt his ability to practice without major conflict with his patients and their best considerations in care.

The history of Medicine from early eras still carries some “take home messages and principles” we should stray from at our peril... and this applies to the Hippocratic Oath¹, a seminal document on the ethics of medical practice, was attributed to Hippocrates in antiquity although new information shows it may have been written after his death. This is probably the most famous document of the Hippocratic Corpus. While the Oath is rarely used in its original form today, it serves as a foundation for other, similar oaths and laws that define good medical practice and morals. Such derivatives are regularly taken today by medical graduates about to enter medical practice and some have suggested a Hippocratic Oath be established for scientist.²

The Hippocratic Oath in one of its derived form

[Classic translation into English]:³

I swear by Apollo the Physician and Asclepius and Hygeia and Panacea and all the gods, and

goddesses, making them my witnesses, that I will fulfill according to my ability and judgment this oath and this covenant:

To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art – if they desire to learn it – without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken the oath according to medical law, but to no one else.

I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.

I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect. In purity and holiness I will guard my life and my art.

I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work.

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Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves.

What I may see or hear in the course of treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep myself holding such things shameful to be spoken about.

If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot.

In the 1870s, many American medical schools chose to abandon the Hippocratic Oath as part of graduation ceremonies, usually substituting a version modified to something considered more politically and medically correct, or an alternate pledge like the Oath of Maimonides.⁴

The Hippocratic oath has been updated by the Declaration of Geneva. In the United Kingdom, the General Medical Council provides clear modern guidance in the form of its *Duties of a Doctor*⁵ and *Good Medical Practice*⁶ statements.

Physician Owned Distributorships (PODS).^{7,14,15}

It is a controversial area, with many states struggling as to their legal status. In addition, questions are being raised as to the moral issue of physician's involvement.

There is no question that we have seen a power inversion in the health care field with insurance carriers, hospital administrators and legislators (both state and federal) introducing laws to reduce the "rights" of medical professionals to earn reasonable income provoking schemes to extend medical income earning in less traditional ways as a reactionary defense. Additionally, we are now faced with non-medical personnel making medical decisions that can and do effect more than just that of health care cost.

History teaches us in medieval times and forward the emerging physician prescribed, made and sold his own "remedies" but was supplanted by the later alchemist and history shows that in medicine, as in

life, once you vacate a fertile field another species will soon fill it and produce in your absence.

In orthopaedics we have slowly resiled from rehabilitating our own patients and that void has been filled by the creation of rehabilitation specialists and we have improved our lot as modern orthopaedic surgeons see it by supers-specializing and in so narrowing our individual skill base from the breadth of our education programs we were involved in, left fertile apertures for lesser entities in podiatry, sports medicine variants and musculoskeletal exponents to promote themselves into traditional orthopaedic areas often more effectively than we have defended our skill base and (rightful) dominance.

Recent historical practices from the 1960s and 1970s showed that orthopaedic surgeons bought not only their soft goods (slings, splints, etc.) but also their total hip implants. Those were the days that the Charnley, Müller and Bechtol Hip Systems were sold non sterile wrapped in cheese cloth pouches with a few instruments also in soft cloth wrapping sold to the surgeon and he carried them around in the trunk of his car going to his hospital.⁸ So historically there is a precedent for orthopaedic surgeons, general surgeons and general practitioners to buy their own supplies and sell them to their patients. So way is this practice wrong today?

If we remember back in the 1950s to the 1980s it was considered honorable to be a physician. No one accused physicians of making too much money and certainly the reputation of this group of individuals was above reproach, hard working and dedicated.

Historically, surgeon designers were just that designers of product build off the need to provide solutions for the needs of the patient. Charnley, Bechtol, Townley, Müller were true designers of their product and they made money (royalties, consulting fees, ownership equity) off their product. However, as the competition got more intense industry as always became more creative. Under contract law it was legal to enter into a services contract with well know surgeons to champion your product. Royalties were now being paid legally for marketing and clinical/surgical related services.

During these boom years the orthopaedic surgeon community sat back as a group and let the fee for serves model deteriorate.^{9,10} By the 1980s the health

care industry became big business with big money and everyone was out to get a piece of the pie. Abuses and greed were being seen at all levels of the health care field. The Justice Department found many faults on both the side of industry and that of the surgeon community.¹¹ Some suggest that if orthopaedic surgeons followed the 1956 American Medical Association instruction “Physicians may not take money except for direct patient care services,” the embarrassment of a Justice Department inquiry could have been avoided”.¹² New standards have been established by industry, professional societies, hospitals, academic institutes, journals and governing bodies restricting certain activities and establishing full disclosure policies.¹³

One of the more restrictive policies that went into effect was the restriction of payment for non-developmental intellectual property (Ip) activities. The Justice Departments policy on royalty payments was now restricted to development and licensing rights of that Ip to a commercial business. No longer could surgeons become champions of a product and receive royalty payments as a result of marketing related activities. Restrictions were also placed on surgeon consultants and the level of their fee structure.¹³

Surgeons were now faced with a declining fee for services model and some of the lucrative business relationships of the past with industry gone.

There are still two institutions in our opinion that need oversight the hospital and the insurance carrier. It is interesting to note that with the so-called run away health care cost that we are seeing an unprecedented expansion at the hospital level. Private rooms, automated robotic inventory systems, marble floors, shopping centers, flat screen televisions etc. throughout the facility. We are also seeing a restriction of fair trade by the hospital with policies that restrict newer companies and technology from getting into the hospital.

Third Party Influence is also flexing its muscle. With the rise of medical insurance, another aspect of personal responsibility for costs of care waned, similar to the rise of social welfare from which has gone our parents sense of guilt if receiving it to a notion of “right” to get it and so in health care as a right instead of a privilege to which we contribute by lifestyle and choice by and large other than for a few of society’s number who are dealt a bad hand at

birth or through unavoidable misfortune whom we all want to assist.

The insurance company has recognized the strength of society demanding access to health care and with the Affordable Heath Care Act¹⁶ now the law of the land has moved to take advantage of this situation. We are seeing the insurance carrier and health care industry (Drugs & Devices) negotiate directly side stepping both the surgeon and the hospital. In our opinion both the government and insurance industry would like to make all surgeons and all devices generic in order to pay the lowest possible price. They do not want to acknowledge training, experience, features and benefits have an added value. So with the continued erosion of fee for services some are looking aggressively how to supplement their income.

Today we are faced with a very different model and issue as compared to the physician of the past. Hospitals have access to top implants and products and do not need the physician to be the go between. The implant company goes directly to the hospital and supplies product lines that far exceed what the old-timer and even modern time physician can supply. These companies are supplying what is considered top line and monitored with tight quality control. The “pods” that we have seen offer a single line of hip or knee with no revision options. These product lines are customarily 20 years old design and hence don’t answer the modern design needs expected today. Secondly and possibly more importantly, the quality of the devise often meets only the minimal standard. ASTM, ISO and FDA requirements are the basic steps necessary for product approval. Often these organizations do not offer advanced biomechanical testing or post-market surveillance. This is becoming a new requirement throughout a number of countries including the US with the FDA’s recent post market surveillance requirement on MoM bearings. Often when discussing quality issues with certain directors of a “pods” about the quality of their product they are in the dark. One example: One of our Co-authors asking a Director of a Pod about the quality of his polyethylene used, he replied: “I am being told it is just like one of the first generation highly cross linked polyethylene”. This was followed up with how do you know? His reply was that he really didn’t. There were no tribology testing or clinical papers to give him assurance of quality. The

real test of quality of a product is its performance lifespan. Unfortunately the inferior quality may not show up for 5 years after which someone else pays for the revision.

From the total joint surgeon's perspective, most never go into a primary or revision cases without anticipated plan A through D. For example, modern knee designs and product lines offer multiple articulations and components to allow for the unexpected finding in the middle of the case. This allows the surgeon to adapt to the particular instability and solve it often times with just a polyethylene design change. If you are working with a "POD" knee, you only get one femoral design and one polyethylene style. This does place an added burden on the hospital to make sure back up material is available. Smaller community hospitals do not routinely carry back up inventory. We all know that anything and everything can go wrong even in a routine primary total joint surgery. No surgeon should expose his or her patient to a potential harmful situation without proper backup plans.

The surgeon is often faced with today the hospital administrator restricting the selection of devices based off contracts and bundling of products. This non-medical practice can and has an effect on altering a surgeon's treatment care plan. The decision on medical devices should not fall to non-medical personnel (government, hospital, or insurance companies).

Over the last few years Physician Owned Distributorship Models (PODS) started appearing. This was very surprising to me with the recent Justice Department probe into both the pharmaceutical and medical device industry. Certainly the last decade has seen a considerable erosion of public opinion concerning ethical behavior in the health care field. No longer does the physician sit on a pedestal.

So why would some surgeons think this business model of buying product and selling the product that you use to your hospital would be acceptable to public opinion??? Remember it is not allowable to pay a surgeon a royalty on product he uses so why would he think he could receive a commission on what he uses.

Tom Scully a senior counsel at the law firm Alston & Bird who headed the Medicare program from 2001 to 2004. "You can't possibly think this is OK." "I understand that the docs feel squeezed and want to make more money, but they're racing toward a cliff. This can't possibly hold up."⁷

Some physician owners argue that they have a legal opinion and they are safe. Many lawyers are not sufficiently sophisticated or knowledgeable about the nuances of the Anti Kickback Statute (AKS) to render a reliable opinion. Others are willing to tell their clients what they want to hear. Who gets in trouble if your legal opinion is wrong? Not the lawyer, you the Physician "investor" are held accountable.

"Insurers Pay Big Markups as Doctors Dispense Drugs"

The New York Times recently ran an article¹⁷ on this subject taking a very critical point of view. Some physicians carry and sell drugs directly to the patient. This is often done as a service of convenience to the patient and many specialty physicians like plastic surgeons and dermatologist supply specialty products not available at drug stores.

There are also a growing number of physicians along with drug distributors that are setting up shop to dispense drugs on a larger scale directly to the patient. At a time of soaring health care bills, some critics outraged at this practice are asking for government reform restricting physicians from the practice of dispensing drugs.

We are suggesting that there can be legitimate reasons for physicians to maintain the privilege of supplying drugs to their patients. However, runaway profits that take advantage of the patient must be stopped.

What in our opinion should happen is the same common sense approach used to control medical device cost at hospitals. A capitation system needs to be in place along with a full disclosure policy.

Allow physicians to carry and sell drugs directly to the patient with a maximum captivated selling price. Let's say the price is based off local fair market value not to exceed plus twenty percent (+20%). There must be a full disclosure statement posted and presented for the patient's acknowledgement

and signature. This policy would prevent run away profits being made by the physician and taking advantage of their patients. You can go as far as requiring physicians who want to dispense drugs to require them to post full disclosure on their web site stating their selling price vs. fair market value.

Yes, there are some loopholes that would need to be fixed such as *average wholesale price*, but this can be done with very reasonable changes to current state regulations. In states that are refusing to restrict runaway physician charges, there needs to be more public awareness brought down on their refusal. Public opinion will demand proper controls put in place. If the states find some legal loophole not to address these runaway charges then at least legal demand that the physician post full disclosure will help inform the patient.

Let's fix the abuse and not overreact to a potential benefit for many patients.

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