Current Otorhinolaryngology Reports (2023) 11:240–244
https://doi.org/10.1007/s40136-023-00472-3

Emerging Conflict of Interests for the Rhinologic Surgeon Entrepreneur

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Accepted: 18 June 2023 / Published online: 28 July 2023

Abstract

Purpose of Review Many rhinologists are inspired thinkers and come up with ideas that have the potential to create novel technology or devices which are worthy of introduction into the commercial arena. There are many ethical, financial, sociological and academic problems which need to be considered in this complex legal arena.

Recent Findings Research fraud is now an increasing reality which makes investors and colleagues cynical of initial claims of effectiveness. Doctors are also bound by ethical obligations which do not necessarily apply to others in the medical device and therapeutic industry. Whilst individuals may dream of the "get rich quick" outcome because of their intellectual property, unfortunately, the reality could not be further from the truth.

Summary In this article, we will attempt to talk through all the various pitfalls that may be encountered and suggest some ways of minimising ethical, psychological, financial and academic pitfalls which may trip up our budding rhinological entrepreneur along the way.

Keywords Innovative therapies · Investigational treatments · Medical device · Otolaryngology · Controlled clinical trial · Healthcare fraud

Introduction

Rhinology has evolved from a relatively basic specialty with head mirrors and forceps into today's technology-rich environment utilising endoscopes, topical therapies and advanced scientific methodology such as lasers, plasma, computer-assisted surgery, robotics and virtual reality [1]. This technology is not just used in the operating theatre but also in the clinic/office and community post-operative patient management areas [2].

Many of our patients have chronic diseases requiring multiple visits and/or procedures. They frequently require ongoing long-term medical management to control diseases which are essentially "man versus environment" [3]. The new millennium has seen an exponential increase in technological growth, not only in medicine but throughout our whole society [1]. The expansion of start-up firms both in Silicon Valley and in other technological hubs around the world has been nothing short of monumental. In addition to numerous success stories, there are of course multiple examples of failure, bankruptcy and even criminal prosecution from misinformation, fraud and deception [4].

Academic rhinology has a heterogenous spectrum of employment around the world [5]. Whilst in the USA, research/teaching clinicians are employed by the university [6] which then provides a remuneration package which is frequently based on their ability to generate private income. Elsewhere in the world, academics are allowed limited private practice outside the university which then pays them a relatively minimal based salary. In some countries, private practice is completely prohibited, and rhinologists are employed solely for the treatment of publicly funded patients. As such, it is not uncommon for even the most successful academic rhinologists to earn significantly less (either through their base salary or in total with external private income) than their counterparts in full-time private clinical practice [7]. It is therefore not surprising that academic rhinologists seek to improve their income by consultancy contracts and/or commercialising their intellectual property wherever possible. Within OHNS, academics with greater industry funding have been demonstrated to achieve higher academic output [8]. Whilst this may seem to be a perfectly reasonable and honourable goal, we must always

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remember that doctors have ethical responsibilities which do not necessarily apply to other individuals in the commercial technology space. The "fake it until you make it" aphorism is adopted by many but would not be regarded as a positive professional attribute by most medical regulatory authorities or the general public [9]. In this article, we attempt to unravel the various issues surrounding the commercialisation of rhinological intellectual property and suggest areas where individuals can avoid problems whilst navigating through this complex maze by developing some foresight and planning.

Intellectual Property Protection

Laws regarding intellectual property (IP) protection vary significantly around the world [10]. There are also certain areas of the globe where it could be argued that there is no IP protection whatsoever [11]. Patent laws are so complex that most universities and academic institutions will have legal experts who are familiar with the various IP legislation, both in their home countries and overseas. Whilst this is a first step along the road, it is not uncommon for the services of a more experienced (and therefore more expensive) external IP lawyer to be required at an early stage in obtaining suitable IP protection for your amazing idea/device or therapy. In the USA, patents are legally allowed to be relatively broad, whereas in other jurisdictions, a researcher is required to be much more specific in how a patent will be applied for it to pass the required statute. It is therefore possible for a rhinological invention to be commercially viable everywhere else in the world but then not be commercially possible in North America because it is covered by a more broad-reaching patent which encompasses it, thereby preventing its use in that jurisdiction without paying some sort of compensation to the encompassing patent holder. As such, this could significantly affect the commercial viability of a product. One must also remember that for a patent to be lodged, the IP involved should not currently be available in the public arena. Simply presenting anything regarding the IP at a meeting and most definitely the publication of a paper in an academic journal would prevent lodgement of such a patent. This needs to be considered prior to the release of any results from what may seem like an exciting early research project with commercialisation potential [12]. It is therefore recommended that if the rhinologist feels that their research has any commercial viability whatsoever that they contact their institution's translational research team as early as possible to ensure that they do not miss the boat in terms of patent lodgement and critically important future IP protection [13].

Research and Integrity

If an idea has the potential for significant commercialisation, there is always a conflict of interest between presenting 100% accurate and non-misleading research data versus any potential for a reduction in external financial interest [14]. There are certainly examples of research presentation/publication being economical with the truth whilst not exactly lying or committing any legal crime whatsoever [15•]. Where the research is performed in the same institution as the beneficiary of commercialisation, in order to maintain credibility it is critical that as much external oversight into the preparation and validation of the data is performed [16]. If you are in a position where others may challenge your data arguing you have a commercial conflict of interest, give some thought to possibly referring a subset of samples to an external independent laboratory for verification and validation [17••]. Ideally, the method of choosing such a subset of data/samples should be chosen by the independent lab rather than the researcher themselves. Whilst it may seem unimaginable that researchers would present falsified data, there are numerous examples whereby this has been the case [18••]. It has been estimated that 14% of research papers in the anaesthetic field contained false data (with a further 8% categorised as "zombie"). When trial data was available, a remarkable 44% had untrustworthy data with a further 26% zombie trials [19].

One might think that an Institute's Clinical Review Board or Ethics Committee would randomly examine data produced by their researchers. Certainly, in my former public hospital, there was neither the funds nor any real desire for the Ethics Committee to undertake this role. From personal communication with other rhinologists worldwide, it would appear this rarely, if ever, occurs. It is purely left up to the individuals concerned to manage the integrity of their data. Whilst leads of research teams might wish for the highest ethical and research standards within their department, one can imagine a budding doctoral candidate realising they are going to produce negative findings and then slightly twist the results in either a minor or major way to completely change the external view and perception of the research into a positive one. This would then have a major positive effect on that individual's future career [20].

Whilst not officially illegal, even failure to reveal negative results which may not have been submitted for publication could be regarded as false disclosure when an external company is involved for potential purchasing of the IP concerned [21]. There have been numerous court cases recently where individuals have faced criminal charges for not performing full disclosure where medical companies

and IP have been sold to a third party [22]. If an RCT is to be performed on a product approaching commercialisation, researchers should give great thought to involving other third-party organisations with an independent safety monitoring board to report on data credibility and adverse advents. Given the exponential increase in research fraud [15•], it is natural to be cynical of a product which has not only been conceived in an institution but then patented, researched and commercialised without any form of external verification of the data whatsoever.

Offshore Liabilities

Most academic institutions have some form of profit-sharing clause in employees' contracts for the IP they generate. It is not unreasonable for the university to require reimbursement for the investment, salaries, and floor space that they supply for the generation of such IP. Nevertheless, many academic contracts may not be completely watertight when regarding companies that are overseas or even in offshore tax haven locations. As a bona fide clinical academic, it may be tempting to establish offshore companies to try and minimise the commercial monies allocated to the university and preserve more to the individual. This behaviour would probably be regarded as highly inappropriate and unethical by the medical fraternity, not to mention medical boards and registration authorities. "Trial by media" is not a pleasant experience for anyone involved [23], and an academic's credibility could be permanently damaged if revelations about offshore dealings were to be revealed in the media. It is also possible that many academic institutions would not react favourably to disclosure that their academics have been trying to deny them their due income by the establishment of offshore companies in this regard.

Confidentiality and Non-Disclosure

It is now common for individuals to be required to declare consultancy agreements and financial connections when presenting research data at research meetings and on publication in medical journals. Whilst the laws in North America are certainly tighter than elsewhere [24], the exact nature and amount of these financial disclosures are usually hidden from the public eye. The reality is that between 2014 and 2018, $8.4 billion was paid to US physicians [25], and many leading medical organisations have deeply entrenched links to industry funding [26]. Within OHNS, rhinologists receive more payments from industry than any other subspecialty [27]. Whereas research which may benefit an individual for a few thousand dollars may not be of concern to the listener/reader, if the individual concerned was to make 5, 6 or even 7 figures from the IP involved, it is not unreasonable that the independent listening/reading rhinologist would wish to be aware of this when analysing the data and making up their own mind about the efficacy of a product or invention. Indeed, there are numerous examples in the medical world where individuals positively attempt to restrict their financial disclosures in meetings and in journal articles. The case of a journal's Editorial Board member who was in receipt of a seven-figure payment from a device company each year is one notable example [28]. Within the rhinology sphere, I am personally unaware of an individual who has been subject to regulation or presentation and/or publication restrictions because of an absence or incomplete failure to disclose. There is therefore little real incentive for individuals and/or industry to perform full financial disclosure and this is something that is allegedly widely performed [29]. A recent Australian study found that 51.7% of articles contained a false "no conflict" declaration and 43.8% omitted some financial links to the authors [24]. This needs to be borne in mind when listening to presentations and analysing research articles.

Naming Devices Versus Anonymity

Rhinologists are usually extremely proud of their research and rightly so. There is a great temptation to name the IP after the lead investigator and rhinology has an established track record in this regard [30]. Whilst this may be tempting and lead to some form of recognition-in-perpetuity, there are several pitfalls that can arise by going along this route. If the IP has been transferred to a third party and then modified, if the technology is named after the original researcher, is that individual then liable for perhaps less than satisfactory results through modification of the device/IP which may have been beyond their control? This can be extremely frustrating, and there are numerous anecdotal examples whereby an individual has attempted to disassociate themselves with a commercial product, only to find that the company wishes to maintain the name-association for their own commercial benefit. Many rhinologists will be simply happy to receive a payment for their services and then have the product named in a way that is no longer associated with them going forward. This does not prevent the individual for negotiating some form of royalty fees and ongoing payment for each device that is sold/commercialised.

Sustainability

Whereas rhinology used to be a specialty that was not particularly expensive in contrast to other surgical fields, this is no longer the case due to the number of disposable

instruments and single-use devices/products that are currently used in routine clinical practice [31]. Individuals will be more than aware of the amount of waste that is produced both in terms of packaging but also in terms of non-reusability of devices which could easily be used on multiple occasions if appropriately sterilised [32]. Device companies make a considerable amount of money through the compulsory use of single-use instruments and equipment. Producing a device which lasts for 20 years without failing is of poor commercial value to the business model of many major companies. Nevertheless, the European Union Medical Device Regulations has recently regulated that surgical devices will need to achieve new regulatory requirements from May 2025 [33]. This will allow for the reuse of devices which were previously discarded after a single occasion. As individuals, we also need to be aware of our own carbon footprint and impact on the globe. As a profession, we have largely stood by and allowed this snowball of single-use devices and instruments to cascade wildly down the hill whilst standing idly by [34]. Rather than leaving things to the regulators, if the profession were to lead this debate and remain united in the push against single-use instruments, there is no doubt that the industry would be left with no choice but to comply. Multiple-use instruments could easily be developed which would be far more cost efficient to the health care budget [35] but also have far less of an impact on the planet in terms of landfill, recycling and general green effects. Individual rhinologists will of course have their own views on climate change, but we are now living in a rapidly changing environment whereby companies will have no choice but to improve their green footprint if they are to remain as preferred suppliers [36]. As researchers, we are therefore equally morally and ethically obliged to start leading this process by promoting research into areas which are more positive in terms of our future biological footprint and the future preservation of the planet.

Conclusions

Rhinologists are intelligent people who regularly come up with amazing ideas and IP. This can result in a significant financial windfall, not only for the individuals concerned but also for the institutions for which they work. There are not only pitfalls with regard to IP protection but also with respect to external monitoring, research integrity and full disclosure within the academic arena. Doctors who are entrepreneurs need to abide by professional ethical and moral principles which may not necessarily apply to our non-medical counterparts in the bioresearch sphere. As such, there are various things that can be done to protect the individual for future liability, both in terms of accusations regarding non-disclosure of data and transparency. Involving your institution's commercialisation and legal teams at an early stage is recommended along with consultation with trusted peers about the ideal way to proceed in this complex entrepreneurial environment.

Funding Open Access funding enabled and organized by CAUL and its Member Institutions.

Declarations

Conflict of Interest Professor Carney is a Consultant for Invicta Medical, Viatris and Nyxoah. He is a Director of Asia Pacific Otolaryngology Surgical Training which receives or has received funding from Olympus, Medtronic, Smith & Nephew, Cook Medical and Inspire. He is in receipt of research funding from Invicta Medical. Amounts of monies are available from the author upon request. He also reports a leadership or fiduciary role in Federal Australian Committees. And he reports support for attending meetings and/or travel to APOST (not for profit reimbursement for exact costs).

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- •• Of major importance

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