6. BIOMEDICAL LAW AND ETHICS

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Introduction

6.1 The year under review saw perhaps one of the most significant decisions in professional discipline with *Lim Mey Lee Susan v Singapore Medical Council* [2013] 3 SLR 900 ("*Susan Lim*"). This was followed by *Pang Ah San v Singapore Medical Council* [2014] 1 SLR 1094 ("*Pang Ah San*"). There, several aspects of the ethical obligations of medical practitioners *vis-à-vis* the extent to which they may apply novel forms of treatment was extensively examined. This area had previously been considered in *Gobinathan Devathasan v Singapore Medical Council* [2010] 2 SLR 926 ("*Gobinathan Devathasan*") and *Low Chai Ling v Singapore Medical Council* [2013] 1 SLR 83.

Professional discipline

6.2 In *Susan Lim*, the Court of Appeal ruled on 94 charges laid against Lim. Broadly, two categories of charges were alleged. First, there was the allegation that Lim had overcharged her patient in excess of and disproportionate to the services rendered; and second, certain invoices had been rendered which falsely represented that such fees had been invoiced by and/or would be payable to certain named doctors, when she knew or ought to have known that such a representation was not true in so far as she had added a significant and undisclosed mark-up to the actual fees charged by those doctors.

6.3 Perhaps the part of the judgment which carries repercussions beyond this case relates to the practice of charging fees. The court came down in relatively strong terms about the ethical obligation of medical professionals in relation to their fee-charging practices. In brief:

> (a) The court rejected the argument that any agreement on fees could preclude a finding that there was some other objective ethical limit on the fees that a doctor could charge his

patient, even in the context of private healthcare. As the court put it, there existed an ethical obligation on the part of all doctors who practised medicine in Singapore – over and above contractual and market forces (for example, any existing agreement on fees between the doctor concerned and his or her patient) – to charge a fair and reasonable fee for their services: at [26]–[28].

(b) The basis for this objective ethical limit on fees was said to arise from the unique societal position of doctors, which imposes an ethical responsibility in favour of public service and not "merely money-making" or "the advancement of self-serving interests": at [35] and [39]–[42].

(c) A doctor could not, therefore, seek to "take advantage" of his patient monetarily or otherwise; and "excessive overcharging" was a breach of this ethical standard: at [44] and [52].

(d) What constituted a fair and reasonable fee for services rendered would depend not only on the relevant facts, but also on the views of experts in the particular field of practice concerned: at [53] and [72].

6.4 There are a number of respects in which there will need to be further clarification in future cases but two short comments may be raised at this stage. First, although the ethical limit for charging fees is said to be "objective", there was no clear guidance on how this determination was to be made. Understandably, each case will turn on its facts, but the fundamental question is how the value of medical services can be objectively ascertained. The court ultimately held that Lim should not have charged more than $2m in this case but this was not made by reference to any forensic valuation of the services provided or matrix. This suggests the inherent difficulty in being objective about the exercise.

6.5 Second, it is curious that little, if at all, weight is given to the ostensible value the patient places on the medical service. According to the court's analysis, it appears entirely irrelevant what fees a patient may have agreed with his doctor. Yet, if the patient is willing to pay a premium for the service of a particular doctor, it is unclear what the ethical objection in allowing that agreement to stand is. There are hints in the judgment that the court is anxious to protect the patient from possible abuse or exploitation but that appears to be more of an argument in favour of ensuring that fee agreements are properly arrived at rather than holding that they are irrelevant altogether.

6.6 It has been suggested that if the dispute is really only concerned with an issue of quantum, this is perhaps better left to some form of

taxation process that could be set up within the Singapore Medical Council ("SMC"): see Rebecca Chew, "Doctor's Fees after Susan Lim's Case – Implications for the Medical Profession" *SMA News* (November 2014) at pp 24–27. This is an idea worth exploring, thus leaving the professional disciplinary process to address only cases where there has been dishonest exploitation of the patient or deliberate overcharging.

Ethical obligations in relation to novel treatments

6.7 Clause 4.1.4 ("the Clause") of the SMC's Ethical Code and Ethical Guidelines ("ECEG") on "Untested practices and clinical trials" ("the Caption") deals with the permissibility of prescribing treatment(s) not generally accepted by the medical profession. This three-paragraph clause reads (the terms in italics were considered by the Court of Three Judges):

Paragraph	Text	Reference
1	A doctor shall treat patients according to generally accepted methods and use only licensed drugs for appropriate indications.	"The Prescription"
	A doctor shall not offer to patients, management plans or remedies that are not generally accepted by the profession,	"The Proscription"
	except in the context of a formal and approved clinical trial.	"The Exception"
2	A doctor who participates in clinical research must put the care and safety of patients first. If a doctor wishes to enter a patient into a *clinical trial*, he must ensure that the trial is approved by an ethics committee and conforms to the Good Clinical Practice Guidelines. In addition, informed consent must be obtained from the patient.	–
3	It is not acceptable to experiment or authorise experiments or research which are not part of a formal *clinical trial* and which are not primarily part of treatment or	–

	in the best interest of the patient, or which could cause undue suffering or threat to the life of a patient.	

6.8 In *Pang Ah San* (above, para 6.1), the medical practitioner ("Pang") was charged for breaching the Clause by providing a patient treatment (a loop Percutaneous Endoscopic Gastrostomy ("loop-PEG") procedure) not generally accepted by the profession outside the context of a formal and approved clinical trial. The patient had required permanent tube feeding after a stroke. Pang recommended the loop-PEG tube as an alternative to the standard Percutaneous Endoscopic Gastrostomy ("PEG") tube. Two days after he performed the loop-PEG procedure on the patient (with her family's consent), her condition worsened and she later died.

6.9 Until the patient's death, Pang had performed 50 standard PEG procedures. These standard procedures had been used safely before, worldwide, for about 30 years. The loop-PEG procedure performed on the patient was, however, only the third time it had been performed worldwide. Pang had also performed the two previous loop-PEG procedures. The loop-PEG tube was Pang's invention, for which he had filed a patent application in October 2007, some nine months before he performed the loop-PEG procedure on the patient.

6.10 Finding Pang guilty of professional misconduct, the disciplinary committee ("DC") observed that he had intentionally and deliberately ignored his ethical obligations as stated in the Clause. The standard PEG tube, which had been used for a long time, was considered an established patient-feeding method. Although the loop-PEG tube served similar objectives, it was a novel device with a different design. All the experts had also agreed or did not disagree that:

(a) until they were engaged as experts, they had never seen the loop-PEG tube;

(b) apart from Pang's "self-serving articles", there was no other medical literature available on the loop-PEG procedure/tube;

(c) even with its disadvantages, the standard PEG tube was the generally accepted device; and

(d) apart from Pang, they knew of no one else using the loop-PEG procedure/tube.

6.11 Affirming the DC's decision, the court clarified several aspects of the Clause and made a number of important observations. It also set

out a useful three-stage framework to decide if the Clause is breached (*Pang Ah San* at [73]):

> (a) whether the rendered treatment is significantly different from the standard treatment;
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> (b) if the rendered treatment is significantly different from the standard treatment, does it constitute treatment "not generally accepted by the profession" ("innovative treatment") and hence trigger the prohibition against such treatment; and
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> (c) if the rendered treatment constitutes innovative treatment, does it constitute therapy administered in the patient's best interests so as to exempt it from the prohibition against innovative treatment.

Scope of "remedies"

6.12 The particulars of the charge preferred (above, para 6.8) only related to that part of the Clause on offering "remedies". It was argued that the DC had erred in law because the loop-PEG procedure did not come within the meaning of "remedies" as it was not a medicinal product capable of a "clinical trial". The phrasing of the Exception suggested that "remedies" had to be capable of a "clinical trial". However, at the time the loop-PEG procedure was performed, it did not fall within the Medicines Act (Cap 176, 1985 Rev Ed) or the Health Products Act (Cap 122D, 2008 Rev Ed), the only two statutory regimes regulating clinical trials. The loop-PEG procedure was hence incapable of a "clinical trial" and so did not fall within the meaning of "remedies". Dismissing this argument, the court held:

> (a) The ordinary meaning of the term "remedies" embraces a very broad category of cures or treatments and includes (*Pang Ah San* at [25]–[26]):
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> (i) the loop-PEG procedure;
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> (ii) other surgical procedures; and
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> (iii) uses of medical devices.
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> (b) The Exception does not limit the application of the Proscription to only "remedies" capable of a "clinical trial". The Caption prefacing the Clause indicates that it is the safety of the remedy, evidenced by the profession's general acceptance, which determines permissible usage. Hence, even if a particular remedy is not capable of a "clinical trial", it is still caught by the Proscription: *Pang Ah San* at [28].
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> (c) The ECEG seeks to uphold trust and confidence in the medical profession by outlining standards of good medical

practice which all doctors should apply in all areas of their clinical practice. The Clause, in particular, aims to ensure that patients suffer no harm. Hence, whenever appropriate, patients should be treated with time-tested methods where the benefits and risks have been well researched and documented. The purposes of the ECEG and the Clause are better served by reading the Clause to prohibit any form of medical practice that was not generally accepted. This interpretation applied *a fortiori* to the loop-PEG procedure which involved the surgical insertion of a device and so carried a higher level of risk than a non-invasive procedure: *Pang Ah San* at [29].

Scope of "clinical trial"

6.13 The court also observed that although the existing statutory regimes for clinical trials did not apply to the loop-PEG procedure (above, para 6.12), this did not mean that the procedure was incapable of a clinical trial or that a clinical trial was not required. The term "clinical trial" in the Clause merely refers to any trial (*Pang Ah San* at [30] and [70]):

(a) which is "approved by an ethics committee";

(b) which "conforms to the Good Clinical Practice Guidelines" (where applicable); and

(c) where the patient's "informed consent" has been obtained.

6.14 The court observed that although the "Good Clinical Practice Guidelines" appear to apply only to drug trials, this did not mean that the Clause also applies only to drug trials. Reviewing guidelines issued by the National Medical Ethics Committee and the Bioethics Advisory Committee that had been disseminated to the medical profession by the Ministry of Health, the court noted that the medical community was generally aware that clinical trials were not limited to drug trials, and could also be employed for new medical devices and procedures. Pang could thus have applied to conduct clinical trials on the loop-PEG procedure, after applying for review and approval from the relevant Institution Review Board ("IRB"): *Pang Ah San* at [30]–[40].

Meaning of "not generally accepted by the profession"

6.15 It was argued that the DC had wrongly interpreted the term "not generally accepted" to mean "not generally known" or "novel". It was contended that this interpretation:

(a) would stifle all innovative treatment, that was part and parcel of medical practice, unnecessarily; and

(b) was inimical to the best interests of patients since it would expose surgeons to disciplinary action each time they varied a surgical technique, a flexibility required in surgical practice.

6.16 On the basis that a better policy balance would be struck between promoting innovation and ensuring that patient safety was not compromised, it was submitted that the term "not generally accepted" should be interpreted to mean "generally rejected" or "generally disapproved".

6.17 In *Gobinathan Devathasan* (above, para 6.1), the court had endorsed (at [46]) the views of the experts who had testified before the DC that novel treatments could become "generally accepted", provided that (the "*Gobinathan* test"):

(a) there had been at least "one good study";

(b) the results of the study could be replicated and reproduced under the same sort of like treatment parameters and conditions;

(c) the study had been written up in publications and presented at meetings;

(d) the study had received peer review;

(e) the study had "clear-cut results" and the sample had been "statistically significant"; and

(f) the study had some form of controls, such as randomised double-blind trials.

6.18 In *Pang Ah San*, it was contended that the *Gobinathan* test had been crafted to apply to mass-produced and standardised treatments like drugs and devices. As such, this test should not be applied to surgical practice as that would lead to inappropriate requirements. For instance, the need for a "statistically significant study" would be onerous in surgical practice where treatments are customised to suit a patient's unique conditions. It was further submitted that the test should instead be that stated in *Khoo James v Gunapathy d/o Muniandy* [2002] 1 SLR(R) 1024 for determining whether a doctor has breached the tortious duty of care owed to his patient (*viz*, whether there is a respectable body of medical opinion, logically held, that supports a doctor's actions).

6.19 Rejecting these proposed tests (above, paras 6.16 and 6.18), and affirming the DC's decision that the loop-PEG procedure was "not generally accepted by the profession", the court observed that:

> (a) The concept of "general acceptance" in the Clause contains a scientific aspect and is not a purely empirical issue. Hence, a treatment may be "not generally accepted by the profession" if it is deemed to be unethical or illegitimate, even though a significant number of doctors may be providing it. That said, where the overwhelming majority of the medical profession endorses a certain treatment, this is *prima facie* evidence of general acceptance by the profession, especially if such endorsement has been over a substantial period of time: *Pang Ah San* at [50].
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> (b) The purposes of the ECEG and the Clause (above, para 6.12(c)) are better served if the term "not generally accepted by the profession" means "not generally known or used". This requires an *ex ante* acceptance of the treatment by the medical profession (*ie*, a positive act of acceptance) and not a lack of rejection of the treatment or an *ex post* acceptance. A novel treatment, by its very definition, thus cannot be said to be generally accepted: *Pang Ah San* at [54].
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> (c) Quite apart from the medical profession's *ex ante* acceptance of a particular treatment, that treatment can be considered "generally accepted" if its potential benefits and risks and the ability to control these are approaching a level of predictability acceptable to the general medical community. Standard treatments, synonymous with treatments "generally accepted by the profession", may nevertheless lose their status of being "generally accepted" if (*Pang Ah San* at [56]):
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> > (i) there is a rejection of the standard treatment by the profession; or
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> > (ii) the underlying assumptions about the safety and efficacy of the standard treatment ought to be seriously questioned given advances in medical knowledge, provided there are viable alternatives to that treatment.
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> (d) A particular treatment will only be caught by the Clause if it is "significantly different" from the standard treatment. Where the treatment rendered is merely a variation or adaptation of the standard treatment to suit the individual patient's circumstances, it may be taken to be similar to the standard treatment and it will not be caught by the Clause. Factors to be considered in assessing whether a particular

treatment is "significantly different" from the standard treatment include (*Pang Ah San* at [57]):

(i) the increase in the amount of risks;

(ii) the addition of new types of risks; and

(iii) if there is a significant increase in the degree of ignorance of the risks.

(e) The *Gobinathan* test can be used to decide whether a particular treatment constitutes innovative treatment. Hence, once it is determined that a particular treatment departs significantly from the standard treatment, that treatment will constitute innovative treatment and will generally be caught by the Proscription if (*Pang Ah San* at [57]):

(i) it has not been validated by reliable research methods;

(ii) it has not earned the clinical community's firm basis of support; and

(iii) there is insufficient evidence to support its safety.

(f) Innovative treatment may only be given (*Pang Ah San* at [57]):

(i) in the context of a clinical trial; or

(ii) as part of a one-off therapy before conducting a clinical trial.

6.20 Here, the argument referring to the flexibility inherent in surgical practice (above, para 6.15(b)) did not apply to the loop-PEG procedure because although it involved a surgical procedure, the focus was on the employment of the loop-PEG tube, a medical device. The relevant surgical procedure was merely a means adopted to facilitate the insertion of this device. As the use of the loop-PEG tube significantly increased the risks of leakage of gastric contents into the peritoneal cavity, the loop-PEG procedure was significantly different from the standard PEG procedure/tube: *Pang Ah San* at [58].

6.21 Applying the *Gobinathan* test (above, para 6.19(e)), the court agreed with the DC that the loop-PEG procedure was innovative treatment (*Pang Ah San* at [79]):

> Applying the factors in *Gobinathan*, the fact that there was no other medical literature available on the loop-PEG other than the articles written by [Pang] … is relevant. The fact that the experts had never seen (or even heard of) the loop-PEG device prior to their engagement … supports the finding that the profession could not

> have had the opportunity to accept the new procedure. The fact that the experts did not know of anyone else using the loop-PEG … supports the finding that the profession had yet to accept the new procedure. On the other hand, the fact that the generally accepted device was the standard PEG … seems to be a neutral factor because it is conceivable that the profession could accept more than one device, and the fact that the standard PEG was the generally accepted device does not ineluctably mean that the loop-PEG device could not be generally accepted as well.

Therapy administered in patient's best interests permitted

6.22 Before the court, it was argued that para 3 of the Clause created a further exception to the Proscription, such that experimental treatments not part of a formal and approved clinical trial were permissible if they were part of treatment and done in the patient's best interest.

6.23 Taking a contextual reading of the Clause, the court held that if it can be established that the experimental or innovative treatment rendered is therapy administered in the patient's best interests, that treatment is exempted from the prohibition against "remedies that are not generally accepted by the profession" (*viz*, the Proscription). However, where it is established that a doctor rendered treatment that was not generally accepted by the profession, the burden is on the doctor to prove, on a balance of probabilities, that the treatment is part of therapy administered in the patient's best interests: *Pang Ah San* at [68] and [108]. In so holding, the court distinguished between research and therapy:

> (a) While therapy is patient-centric and undertaken primarily to benefit the patient, research is undertaken primarily to generate new information or test a hypothesis: *Pang Ah San* at [62] and [65].
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> (b) The doctor-patient relationship *vis-à-vis* therapy is fundamentally different from the researcher-subject relationship *vis-à-vis* research. While the researcher's interests may not be entirely aligned with those of the research subjects, the doctor-patient relationship must be intended for the patient's direct benefit and best interests. Research subjects usually do not benefit directly from the researcher-subject relationship in any way. Medical practitioners who are also researchers must be careful not to confuse their roles and obligations when dealing with patients who may also be their research subjects concurrently. Where the primary purpose for offering innovative treatment is no longer to benefit the patient, but to generate information to test a hypothesis, the doctor morphs into a

researcher, and there may be a conflict of interest: *Pang Ah San* at [66]–[67].

(c) The protection of the interests of patients undergoing treatment under therapy is ensured largely by *post-hoc* regulation via the law of medical negligence and disciplinary proceedings: *Pang Ah San* at [65].

(d) Prospective reviews and approval by IRBs ensure that the researcher is not the sole judge of the ethical acceptability and scientific merit of a proposed research programme: *Pang Ah San* at [67].

6.24 The court noted that while IRBs have a critical role in approving research, it should not be held legally responsible for any unintended consequences arising from the employment of innovative treatment. Rather, it is the researcher/doctor who should be "wholly responsible": *Pang Ah San* at [70].

6.25 The court also observed (at [69]) that it would be prudent for a doctor to seek the IRBs' approval if seeking such approval is not impracticable where the doctor has doubts as to whether an innovative treatment constitutes research or therapy and:

(a) where the standard treatment has not been shown to be ineffective; or

(b) where urgent treatment is not required.

6.26 This distinction between research and therapy was important because therapy is excluded from the regulatory regime which provides for prospective review applicable to research: *Pang Ah San* at [64] and [108]. Here, apart from a bare assertion, Pang had not made substantive arguments as to whether the treatment rendered was therapy. In any event, the court found that the evidence suggested that the loop-PEG procedure was given as part of research and not therapy: *Pang Ah San* at [109].