寰宇醫事裁判

# 罕病孕婦 因藥物副作用猝死判賠

Being Sentenced to Compensate for a Pregnant Woman with Rare Disease who Died Suddenly Due to Side-Effects of Taking Medicine

## 黃浥昕 Yi-Hsin Huang 編譯

平成29年(ワ)第2052號損害賠償請求事件 今和3年2月17日京都地方裁判所



## 摘要

原告A患有罕見疾病,服用Soliris藥物治療。該藥物副作用乃極易誘發腦膜炎菌感染,若懷疑有感染情況則必須立即診察以及投與抗生素。A於懷孕期間服用Soliris,而無副作用出現;惟A產後出現Soliris副作用症狀,經電話聯絡助產士與X醫師,僅判斷為乳腺炎。嗣後A副作用症狀趨嚴而送往急診,經Y醫師診察雖懷疑有腦膜炎菌感染,然因A之WBC值與PLT值仍正常,故未即時投與抗生素治療。最終A因感染與併發症死亡。Soliris說明書已載明若懷疑感染情況即應投與抗生素,被告Y醫師雖主張「懷疑有感染的情況」應為「積極或強烈之懷疑」,但法院認為以一般人對文字的理

關鍵詞:不作為侵權行為(torts with omission)、因果關係(causality)、

醫療水準(medical standard) **DOI**: 10.53106/241553062021090059006



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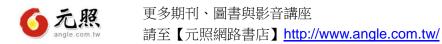
解,應解釋為「無法否定可能有感染的情況」較為合理。因此,Y醫師如有立即投與抗生素,即得避免腦膜炎,故法院判決被告敗訴。

The plaintiff A suffered from a rare disease and needed to take Soliris as the medical treatment. As a side effect. it caused meningitis easily. With suspicion of infecting, it should be diagnosed and give antibiotics. During the pregnancy, A took Soliris without side effect. But she got it after giving birth. After contacting with a maternity assistant and the physician X per phone, she was diagnosed with acute mastitis. Then A was sent to emergency because the side effect had gotten worse. After the diagnosis of the physician Y, meningitis was suspected, but the white blood cell rate (WBC rate) and the blood platelet rate (PLT rate) were still so normal that the antibiotics wasn't be given. Eventually died A because of the infection and complications. According to the instruction of Solirs, antibiotics should be given under the situation of a suspected infection. Even the physician Y as the accused claimed that the situation of a suspected infection should be an active or strong suspicion. But the court found it might be more reasonable, that it, according to the textual realization of common people, should be that a possible situation of infection couldn't be excluded. Therefore, if Y gave antibiotics immediately, the meningitis could be avoided and the Accused lost the litigation consequently.

## 壹、事實概要

## 一、事件概要

罹患罕見疾病「陣發性夜間血紅素尿症」(Paroxysmal



Nocturnal Hemoglobinuria, PNH)的原告A於京都大學附屬醫院就診及生產,產後因腦膜炎感染併發敗血症死亡。原告B、C為A之夫以及長男,以被告醫院醫師及助產師等人有未詳盡告知藥劑副作用、未盡早指示A至急診就醫,以及未及時投與抗生素等過失,要求被告法人京都大學支付共約1億8,750萬日圓的損害賠償金。

PNH為一種罕見的後天性血液疾病,治療藥物為Soliris(Eculizumab)。由於Soliris會抑制補體的免疫作用,使感染腦膜炎雙球菌的風險增加,通常會建議在投藥開始兩週前接種腦膜炎疫苗。投藥後也常出現腦膜炎的初期症狀,包括發燒、頭痛、頸部僵直、畏光、噁心、嘔吐、紫斑等,在疑似感染之際必須立即進行診察並投與抗生素,否則可能於24小時內致死。

A因擔心懷孕過程中,其PNH可能惡化,故於2016年1月 至被告醫院接受孕期管理,同年4月開始接受Soliris投藥,當 時並無藥物不良反應。同年7月31日至8月6日,A則住院生 產。產後的8月22日(死亡前一日)中午,A赴被告醫院接受 Soliris投藥。午後A出現畏寒、頭痛、發燒等症狀,下午16時 左右對其母表示「全身發冷到無法動彈」。A母即致電婦產科 表示,近午時接受Soliris投藥後開始出現劇烈的畏寒,回家後 乳房雖有硬塊但哺乳後馬上就消失了,目前不覺得乳房有疼 痛或發熱,也沒有感冒症狀。助產師聯絡X醫師詢問意見,因 A母還在電話線上,助產師未詳細傳達訊息予X醫師,匆忙表 示「我可以處理」後就掛斷電話,自行推測為乳腺炎,回覆A 「今晚好好哺乳,若明天早上還沒有退燒或乳房有問題,再電 話聯絡。」A聽從指示進行授乳,卻連抱小孩的力氣都沒有, 只能由姊姊協助擠奶,下午18時左右其體溫超過40度。之後 A持續出現畏寒及嘔吐等症狀,下午21時左右A母再度致電醫 院,此時A已有脱水症狀,感覺手麻,乳房無熱感、發紅或硬