學習式判解評析

【醫療刑事法】醫美泿蓮絲注射案：泿蓮絲注射風險與醫療常規之界線*

Litigation of ELLANSÉ Injection in Aesthetic Medical Practice: Reassessing the Legal Boundaries of ELLANSÉ Injection and Medical Standards of Care

張濱璿 Brian Pin-Hsuan Chang*

摘 要

本案涉及醫師於病患鼻部曾植入Goretex永久性物質後，進行泿蓮絲注射而導致不良結果，是否構成業務過失致傷害罪。一審認定醫師未妥善評估患者病史與風險，劑量施打過量，構成過失；二審則認為難以確認泿蓮絲為傷害原因，且醫師施術過程未逾越臨床裁量與醫療常規，改判無罪。本案顯示藥品仿單作為醫

*臺北醫學大學醫療暨生物科技法律研究所兼任助理教授（Adjunct Assistant Professor, Graduate Institute of Health and Biotechnology Law, Taipei Medical University）、馬偕兒童醫院兼任主治醫師（Adjunct Attending Physician, MacKay Children's Hospital）、昶騰法律事務所主持律師（Chairman, Attorney at Law, ChampTime BioMed and Law Firm）

關鍵詞：仿單（package insert）、注意義務（duty of care）、泿蓮絲（Ellansé）、病歷（medical record）、醫療常規（medical standard of care）

DOI：10.53106/241553062025050103005

療常規與合理臨床裁量標準之間的界線爭議，亦反映出臨床診療與法律判斷之交錯與困難。同時亦提醒醫師執業時，需更加謹慎評估風險並重視詳實記錄病歷之重要。

This case concerns whether a physician's administration of Ellansé in a patient's nasal region—previously implanted with a permanent Goretex material—constitutes professional negligence resulting in adverse result. The court of first instance found that the physician failed to adequately assess the patient's medical history and associated risks, and administered an excessive dosage, thereby establishing negligence. However, the appellate court held that causation between the injury and the Ellansé injection could not be conclusively proven, and that the physician's actions did not exceed the bounds of clinical discretion or violate the medical standard of care, ultimately rendering a not-guilty verdict. This case underscores the ambiguity between package insert warnings and the scope of reasonable clinical discretion, highlighting the complex interplay between clinical decision-making and legal assessment. It also serves as a cautionary note to physicians regarding the necessity of careful risk evaluation and the critical importance of maintaining comprehensive and accurate medical records.

壹、案件概述

一、案件事實

被告A醫師為甲醫美診所醫師兼負責人，為病人B以沛蓮絲植入劑（ELLANSÉ-M，下稱沛蓮絲）施行鼻部微整形手術，手術前5個月病人B曾於其他診所（起訴書及判決書未記載是否為乙診所）進行Goretex永久性植入物植入骨膜層下方之隆鼻手術。依據甲診所病歷顯示，當天施打沛蓮絲劑量為0.8 cc。病人B於本次術後發現鼻部紅腫，並有山根過高C型變形之情形，曾以通訊軟體向甲診所詢問（未回診）是否能將沛蓮絲移除。後於手術隔日前往另一家乙診所，該診所C醫師為病人B進行引流手術，排出約0.4 cc之植入物以減輕鼻部壓力。告訴人即病人B向被告A醫師索賠，原要求返還手術費用3萬元作為和解條件，後因故提高索賠費用致無法達成和解，病人B遂向地檢署提出告訴。

經檢察官偵查後，認為被告A醫師本應知患者病史，根據沛蓮絲仿單記載「曾經植入永久性植入物的部位不建議使用」，因沛蓮絲注射點即位於膜層上方而與Goretex植入位置接近，應注意審慎評估是否仍適合注射沛蓮絲之手術風險。若評估後仍認為可注射，則應注意單一注射位置不宜過量。而依當時情形並無不能注意情事，竟疏未注意而於病人鼻馬鞍部皮下單一位置施打過量之0.8 cc沛蓮絲，施打位置過於集中導致注射處壓力過大，未能即時釋放壓力，致手術後患者出現鼻部紅腫與C型變形。認A醫師涉犯修正前刑法第284條第2項前段之業務過失致傷害，提起公訴。

二、爭點與被告主張

本件主要爭點即在於，被告A醫師替告訴人注射沛蓮絲後，造成其受有鼻部紅腫及C型變型等傷害，是否有過失？