

Dr Bryan Smith
Response to QVFA Supplementary Submission 16.7

11 September 2018

Ms Lyn Beverley
Committee Secretary
Senate Foreign Affairs, Defence and Trade References Committee
PO Box 6100 Parliament House
Canberra ACT 2600

Dear Lyn,

Re Senate Inquiry – Use of the Quinoline anti-malarial drugs Mefloquine and Tafenoquine in the Australian Defence Force. – Supplementary Submission made by Major McCarthy (retired)

I understand Major McCarthy (retired) has made a supplementary submission in relation to the oral testimony presented by Mr. Mark Reid to the Committee on the 30th August 2018. The date of Major McCarthy (retired) submission is 6th September 2018.

I have reviewed this submission and am aware that others are also submitting statements to correct some errors and provide some clarification to statements made within the submission. To avoid being redundant, I have confined my comments only to statements involving me directly.

1. 60P was founded by Dr Dow in 2010 while he was an employee of the U.S. Army, directly involved in the development of tafenoquine. While Dr Dow was working on the development of tafenoquine for USAMMDA in August 2014, 60P entered into a cooperative research and development agreement (CRADA) with USAMMDA for the continued research and development of tafenoquine for malaria prophylaxis (Attachment 3). As part of this contractual agreement, USAMMDA awarded 60P with an exclusive license for tafenoquine.

BRYAN SMITH RESPONSE: Dr Dow was never technically and employee of the U.S. Government. He resigned his role as a Contractor several months prior to entering into negotiations with USAMMDA and MRMC. I was not the Decision Authority for either the CRADA or License Agreement discussed here.

2. At the time this license was awarded to 60P, Dr Dow's supervisor was Colonel Bryan Smith, the USAMMDA product manager for antimalarial drugs including tafenoquine. Prior to the award of this contract (as per my original submission, including documentary evidence), Colonel Smith was requested by Commander (ret) Bill Manofsky to approve a follow up vestibular study of the AMI "Study 033" tafenoquine subjects from the 1 RAR Battalion Group in East Timor, to be conducted by Captain (USN) Michael Hoffer a medical doctor specialising in vestibular disorders. Commander Manofsky had already secured the agreement of Captain Hoffer to conduct the study and the necessary funding from U.S. Army Special Operations Command. Colonel Smith simply needed to approve the conduct of this study. The original Study 033 report found that 5% of the tafenoquine and mefloquine subjects experienced vertigo, a vestibular condition. This Committee has heard

extensive first-hand evidence of chronic vestibular symptoms among the 1 RAR trial subjects including dizziness, vertigo, balance problems, hearing problems and tinnitus. The reason that Colonel Smith did not approve this follow up study is that the evidence obtained during the proposed study may have undermined his prospects for successfully registering tafenoquine.

BRYAN SMITH RESPONSE: As detailed above, Dr Dow was no longer an employee under the USAMMDA support contract in place at the time when 60P entered into its CRADA and licensing agreements. As the tafenoquine Product Manager, I was the Chair of the Tafenoquine IPT that Dr Dow provided technical subject matter expertise support to, but I was never his direct supervisor. During my tenure as Tafenoquine Product Manager I did certainly did have discussions with CDR(ret) Manofsky, CAPT Hoffer, and many other stakeholders and experts to more fully understand any and all potential concerns and how best to gather and incorporate the best evidence of tafenoquine's efficacy and safety to support its marketing applications and eventual appropriate medical use.

3. Colonel Smith retired from the U.S. Army at the end of 2015 and was then employed by CNS in Washington D.C. (the same consulting company as Mr Reid), where he continued to work as a consultant on the development of tafenoquine. Mr Smith is now the 60P Chief Medical Officer.

BRYAN SMITH RESPONSE: Since January 2016 I have been employed full-time as the Principal Medical Consultant for Clinical Network Services. Within this role I am contracted to also operate as the Chief Medical Officer for 60 Degrees Pharmaceuticals. Other than my salary as an active duty officer in the U.S. Army, my current Army retirement pay, and my current salary as Principal Medical Consultant for CNS, I have received no other compensation of any kind for the work I have performed for USAMMDA, CNS, or 60 Degrees Pharmaceuticals.