THE MATTER OF THE COLLEGE OF PHARMACISTS OF BRITISH COLUMBIA

AND

ISIDORO ANDRES "RUDY" SANCHEZ, MARIGOLD COMPOUNDING and NATURAL PHARMACY and MARIGOLD NATURAL PHARMACY LTD.

CORRECTED DECISION ON HEARING OF CITATION BY THE COLLGE OF PHARMACISTS: STATUTORY APPEAL RIGHTS ADDED TO ORDER ON AUGUST 22, 2018

(Wayne Chen, Chair, Jody Croft, Howard Kushner)

Hearing Date:	October 16-18, November 6-8, November 14-15, 2017 Vancouver, B.C.
Counsel for the College of Pharmacists of B.C.	Mr. D. Lebans, and Ms. R. Egit
Counsel for Isidoro Sanchez and Marigold Compounding and Natural Pharmacy	Self-represented, did not attend the hearing
Counsel for the Discipline Panel:	Ms. M. Baird, Q.C.

Introduction

On October 12, 2016, the Registrar of the College of Pharmacists of British Columbia (the "College"), pursuant to the instructions of the College's Inquiry Committee (the "Inquiry Committee"), issued a Citation. The Citation alleges that Isidoro Andres "Rudy" Sanchez (the "Registrant"), Marigold Compounding and Natural Pharmacy (the "Pharmacy") and Marigold Natural Pharmacy Ltd (the "Corporation") has committed a number of offences contrary to sections of the Health Professions Act (the HPA"), the Pharmacy Operations and Drug Scheduling Act (the PODSA"), the Controlled Drug and Substances Act ("CDSA"), and the Food and Drugs Act (the "FDA") including regulations under those acts, such as the Marihuana for Medical Purposes Regulations (the "MMPR"), the Narcotic Control Regulations (the "NCR"), the Food and Drug Regulations (the "FDR") and the Natural Health Products Regulations (the "NHPR"). In addition, the College alleges that the College's Professional Practice Policies (the "PPPs"), the Guidelines to Pharmacy Compounding 2006 published by the National Association of Pharmacy Regulatory Authorities (the "NAPRA" Guidelines) and the Policy on Manufacturing and Compounding Drug Product in Canada published by Health Canada (the "POL-0051") have not been complied with. Further, the Citation alleges that the Registrant has failed to comply with both the terms of a Consent Agreement and the provisions of the Inspection Reply Form. The Citation runs for seven pages and has twenty-one charges and fourteen pages of particulars.

A Panel of the Discipline Committee of the College of Pharmacists of British Columbia was appointed pursuant to section 38 of the Health Professions Act to hear and determine the allegations in the Citation issued against Isidoro Andres "Rudy" Sanchez, Marigold Compounding and Natural Pharmacy and Marigold Natural Pharmacy Ltd.

Preliminary Issues

There was a Case Management Conference conducted by the Panel on January 19, 2017. Hearing dates were established for October and November 2017. The College was represented by Catherine Herb-Kelly Q. C.. No one appeared on behalf of the Registrant, the Pharmacy or the Corporation. The Panel received affidavit evidence of attempted personal service on the Registrant. Service was also attempted by registered mail and a copy of the Citation was posted on the door of the Registrant's last known personal address. Registered mail service was also attempted for both the Pharmacy and the Corporation at their last known address. The Panel was satisfied that the College had made reasonable attempts to serve the Registrant, the Pharmacy and the Corporation and proceed to set the hearing dates for October and November. The hearing took place in Vancouver during October and November of 2017.

On the first day of the Hearing, Mr. Don Lebans and Ms. Ruby Egit appeared on behalf of the College. No one appeared on behalf of the Registrant, the Pharmacy or the Corporation. Under Section

38(5) of the HPA, the Panel may proceed with a hearing in the Respondent's absence on proof of receipt of the Citation by the Respondent. The College has provided affidavit evidence of the attempts to personally serve Mr. Sanchez and the serving of documents by regular mail, registered mail and email to the last known address of the three respondents. The Panel is satisfied that the College has taken all reasonable steps to bring the Citation to the attention of the Respondents and that the hearing should proceed.

Counsel for the College advised that the College intended to provide all the evidence by way of affidavits. Under the HPA, Section 38(4.1) (a), the Respondents are entitled to at least fourteen days notice of the College's intention and the Respondents are to be given an opportunity to inspect any documentary evidence. The evidence of the College is that in September 2017, the College arranged through their counsel to serve the Respondents in person and subsequently by mail at the addressed provided to the College by the Respondents. These letters were returned.

Section 38(4.2) of the HPA grants the Panel the power to allow the introduction of evidence that is not admissible under Section 38(4.1). The Panel is satisfied that the College has taken reasonable steps to comply with Section 38(4.1). The Respondents should not be able to prevent the matter from proceeding and the College from relying on documentary evidence in the hearing by the Respondents' failure to communicate with the College and to provide current addresses for service of documents. The last date of communication of the Respondents with the College was September 2014. The Panel will allow the College to rely on documentary evidence, in particular the affidavits of:

1. Ms. Esther Jeon
2. Ms. Valerie Tsui
3. Ms. Polly Graves
4. Ms. Lynn Pollock
5. Ms. Deborah Rees-Lee
6. Mr. Jonathan Lau
7. Mr. Christopher Rose
8. Ms. Kim Seeling, and
9. Ms. Ulla Herlev

In addition, two expert reports, one by Ms. Dana Lyons and another by Mr. Eric Kastango were also tendered and admitted into evidence The Panel is satisfied that all the documentary evidence is admissible as being necessary to ensure that the legitimate interests of the College would not be unduly prejudiced by the Respondents' failure to provide up-to-date information to the College and their non-communication with the College.

The Respondents

There are three Respondents in this matter, the Registrant, the Pharmacy and the Corporation. The Registrant held Full Pharmacist registration with the College from June 2, 1979 to November 30, 2015, aside from a brief period as a Non-Practicing Registrant in 2001. On September 26, 2014, the Registrant was suspended by order of the Inquiry Committee under Section 35(1)(b) of the HPA. That suspension was never lifted. On November 30, 2015, the Registrant failed to renew his registration and was moved to the Former Registrant category. He continues to be in that category. Although listed as a Former Registrant, under both the HPA (Section 26) and the PODSA (Section 1), the term "registrant" is defined to include a "former registrant" for the purpose of the exercise of the College's disciplinary authority.

The Pharmacy, Marigold Compounding and Natural Pharmacy, was licensed as a Community Pharmacy on October 30, 2008 and was located in Courtenay, B.C. The Registrant, during the relevant time period, was the only registered pharmacist practicing at the Pharmacy, and was the manager of the Pharmacy for the purposes of PODSA and the College's PODSA Bylaws. The license of the Pharmacy was suspended on September 26, 2014 under Section 35(1)(b) of the HPA and Section 20(3) of PODSA. On September 30, 2014, the license was not renewed.

The Corporation was the owner of the Pharmacy and the Registrant was its sole director.

The Evidence

College inspectors attended the Pharmacy on three occasions in 2014: March 4 and 5, 2014 (the March Inspections) and again on September 26, 2014. Ms. Jeon, Mr. Lau, Ms. Tsui, Ms. Graves, Ms. Pollock and Ms. Rees-Lee participated in the March Inspections. Ms. Jeon, Ms. Graves, and Ms. Rees-Lee as well as Ms. Fu and Mr. Budd participated in the September inspection. All the inspectors except Ms. Fu and Mr. Budd provided affidavit evidence respecting their inspection including their observations and concerns. The Panel has reviewed all the evidence provided to it. Given the volume of evidence submitted, the Panel has chosen to refer in the decision only to those portions of the evidence that is necessary to provide context to the decision.

Ms. Jeon's Evidence

At the time of the inspections, Ms. Jeon was a Complaints Resolution Officer with the College. She had conduct of the investigation into the pharmacy practice of the Registrant and the Pharmacy and managed the inspections in March and September 2014. Ms. Jeon provided some history in respect of the Registrant and the Pharmacy. In 2010, because of a complaint received by the College relating to pharmaceutical products that were allegedly manufactured at the Pharmacy, a joint investigation by the

College and Health Canada occurred. This resulted in a suspension of both the license of the Pharmacy and the Registrant's registration effective June 14, 2010. A Consent Agreement was agreed to by the Registrant and the Registrant's registration and Pharmacy were re-instated on September 16, 2011. This is the Consent Agreement that is alleged, in the Citation, Allegation 4, as having not been complied with. One of the terms of the Consent Agreement was that the Registrant and the Pharmacy undertook to obtain the requisite Establishment License to manufacture drugs under the FDA and the requisite site license to manufacture natural health products under the NHPR before engaging in the manufacturing of any drug or natural health product.

Ms. Jeon advised that she was the team leader of the March inspection. Prior to the inspection, she identified certain areas of pharmacy practice that required review and delegated each area to members of the inspection team. During the March Inspection Ms. Jeon asked the Registrant if he had obtained from Health Canada an establishment license under Part C of the FDR or a site license under Part 1 of NHPR. Ms. Jeon advised that the Registrant stated he had not obtained either license but was in the process of obtaining these licenses. He also stated to Ms. Jeon that "there was a grace period allowed by Health Canada during which he could manufacture drugs and natural health products without the necessary license". Ms. Jeon subsequently spoke with Kim Seeling, the Regional Regulatory Compliance and Enforcement Specialist and Inspector designated under the FDA for the BC Region for Health Canada. Ms. Seeling advised Ms. Jeon that the grace period described the by Registrant did not exist. Further, Ms. Seeling provided an affidavit advising that no Establishment License under the FDA or site license under the NHPR had been issued to the Registrant or to the Pharmacy.

In her first affidavit, Ms. Jeon advises that she spent most of her time during the March 2014 Inspection in the Pharmacy's Compounding room and manufacturing area. She also advises that she asked the Registrant if he does in fact manufacture drugs and natural health products in the compounding room and manufacturing area. The Registrant advised that he manufactured both drugs and natural health products in those rooms.

Ms. Jeon, in her first affidavit, stated that she seized a number of items from the Compounding Room (Paragraph 38). Examination of the seized products, including the product labels, did not reveal any evidence of a patient-pharmacist relationship between the Registrant or an individual patient to whom these products would be sold. Ms. Jeon further states that in her review of the pharmacy records, she was unable to locate any documentation suggesting that these products had been prepared for specific patients. As a result, Ms. Jeon concluded that the products were manufactured in bulk quantity for sale to customers who did not have a prescription.

Ms. Jeon also inspected an area called the "Second Manufacturing Room" where stock bottles and source materials were stored on shelves. Ms. Jeon advised that stock bottles are products from a manufacturer or wholesaler that contain source material. Source material is used by pharmacists to

prepare other products. There were four shelves that were stocked with NHP that appeared to have been manufactured on site and sealed with “Marigold Compounding and Natural Pharmacy” labels. The Registrant, when asked by Ms. Jeon if the NHPs sealed with the Pharmacy labels are manufactured on site, stated they were.

Ms. Jeon seized one bottle of select items as a representative sample of products contained in the Second Manufacturing Room. Ms. Jeon estimated the total number of products at about 250. In Paragraph 57 of her first affidavit, Ms. Jeon listed 32 sample items seized for further review and analysis. None of the products had any patient specific information on the labels. Many of the products appeared to have been made in bulk quantity.

Ms. Jeon also went into the Dispensary area of the Pharmacy to observe the shelves and check for compounded products containing scheduled ingredients (ingredients that are found in the schedule of the FDR or NHPR and that are subject to the requirement of an Establishment License or site license for their manufacture). She seized several items on the basis that they appeared to have been manufactured on site. Paragraph 63 of her affidavit lists 12 items seized. Ms. Jeon prepared an Investigation Report about her attendance at the Pharmacy on March 4 and 5, 2014. (See Exhibit P to Ms. Jeon’s first Affidavit). She provides a detailed description of the items seized and the infractions (if any) of applicable Federal and Provincial Statutes as well as policies and guidelines. At page 39 of her Investigation Report, she summarizes the infractions observed from the inspection:

33 NHP products manufactured on site without a site license.
13 scheduled products manufactured on site without a drug establishment license
20 products did not have a compounding log
27 products had incomplete compounding log
15 products had labels that were incomplete
1 product had raw materials that were unknown or uncertified
1 product was expired
1 product was labeled in a manner that constitutes infringement of a registered trademark and passing off, and
33 products had inappropriate expiry dates

She stated in her Investigation Report at page 39 that her primary concern from this inspection was “that a vast array of products, ranging from NHP to scheduled products on all levels, are being manufactured on site without valid licenses from Health Canada”. Further, she states that important quality control measures, such as determination of proper expiry dates and reliability of compounding formulations, are not in place raising concerns about threats to public safety. Ms. Jeon advised that the products that the Registrant is manufacturing or compounding are aimed at treating serious health conditions such as heart conditions, epilepsy and hypothyroidism.

Ms. Jeon also attended the Pharmacy on September 26, 2014 along with four other College inspectors. At that time, the Registrant was given a letter informing him that the Inquiry Committee has suspended his registration and the Pharmacy's license pending completion of the Committee's investigation.

Items were seized in the September 2014 inspection by Ms. Jeon and Ms. Deborah Rees-Lee from the Compounding Room, the hallway leading to the Manufacturing Room, the Second Manufacturing Room and a fridge in the room between the Dispensary and the Compounding Room. Approximately 6,000 containers of drugs and NHPs were seized. The College returned some of the seized items to the Registrant's legal counsel on December 22, 2014 but kept approximately 2000 containers of drugs, 1,931 of which were from the Dispensary and Compounding Rooms of the pharmacy. Of those containers, over 300 held drugs that had expired as of September 26, 2014, 642 had no expiry date marked on them and 893 were marked with expiry dates that exceeded the expiration period applicable to the contents. Many containers of drugs had Marigold Pharmacy labels on them; the labels lacked patient names and many were available in bulk quantities.

Ms. Jeon also provided evidence arising from the September inspection respecting the presence of cannabinoid substances at the Pharmacy. She located compounded cannabinoid substances in a fridge located in a room between the Dispensary and the Compounding Room as well as in a fridge in the hallway. These substances were sent to the RCMP who had the samples tested by Health Canada for drug analysis along with three other suspect prescriptions from the Pharmacy which had been subsequently returned by Pharmacy clients to local pharmacists. In a letter to the College (found at Exhibit GG of Ms. Jeon's first affidavit), Constable Grubb of the Comox Valley RCMP Detachment confirmed that the majority of the test results have been received and all tested positive for the presence of THC, a Schedule II substance. Twenty-two separate items were submitted for testing; of the twenty-two, sixteen items were found to contain THC. Six items were food products which take longer to test and the tests were not yet completed when the Constable wrote to the College. The items seized had labels on them that indicated that they were produced by Marigold Pharmacy and had the Registrant listed as the prescriber or pharmacist.

Ms. Jeon also provided evidence respecting the preparation and dispensing of human placenta capsules arising from the September 2014 inspection. Ms. Jeon advised that for the period of 2013 and 2014, the Registrant's PharmaNet records disclose that 88 prescriptions for placenta capsules were dispensed to patients. The Registrant is indicated as the prescriber for approximately 64 of the 88 prescriptions. Ms. [redacted] D[redacted], a registered midwife and Dr. [redacted] B[redacted] are indicate as the prescriber for several of the other prescriptions of human placenta capsules. Both Ms. D[redacted] and Dr. B[redacted] have advised the College that they never prescribed human placenta capsules for the named patients.

Ms. Jeon also undertook, as part of her investigation, to contact physicians who wrote prescriptions that were dispensed at the Pharmacy. Ms. Jeon noticed when reviewing PharmaNet reports that "in many cases, the drug that was processed through PharmaNet was not the product ultimately dispensed by the Registrant" as disclosed by the drug use directions in the PharmaNet report (Paragraph 122 of the first affidavit of Ms. Jeon). Ms. Jeon wrote to over 100 physicians asking them to confirm that they wrote the prescriptions for the drug that was entered into PharmaNet with their name as the prescriber. Approximately 30% of the physicians responded. Ms. Jeon identified, in Paragraphs 124 to 171 of her first affidavit, numerous instances of situations wherein a physician either did not prescribe a particular drug for a specific patient or did not authorize any renewal of the prescribed drug and yet the Registrant dispensed a particular drug for a specific patient or a renewal with the physician named as the prescriber as per the PharmaNet records.

Ms. Jeon also provided evidence of a failure of the Registrant to provide responses to questions posed to the Registrant in emails and letters between March 21, 2014 and January 5, 2015.

Ms. Jeon also attached as an exhibit to her first affidavit, a report prepared by Dana Lyons and a report prepared by Eric Kastango. These reports were tendered as expert reports. The Panel accepted the two expert reports into evidence but gave them little weight and did not rely upon them in making their determinations.

Ms. Jeon, in her first affidavit, provided evidence respecting the seizure of a clear plastic bag containing more than 800 capsules. The bag was labelled Methadone 5 mg. capsules with a patient's name and another separate label showing "200 compounded mixture" which was dated April 17, 2009. Ms. Jeon also seized a vial containing white powder labelled only as "Methadone" and, a clear plastic bag labelled only as "Methadone 5 mg." with a number of 5 mg. capsules inside it. Both items lacked an expiry date or lot number information. A stock bottle of Methadone Hydrochloride 100 mg. manufactured by Medisca that had expired September 2012 was also seized. All the items were seized from a safe located in the Compounding Room.

Ms. Jeon also stated that she had written to Dr. Michael Coughtrie, Dean of the Faculty of Pharmaceutical Sciences at the University of British Columbia to confirm if the Faculty ever had a residency program called "Manufacturing Pharmacy Residency Program". Dr. Coughtrie responded and advised that the Faculty of Pharmacy does not have and never has had a "Manufacturing Pharmacy Residency Program". He did advise that there was a two-credit course called "Manufacturing Pharmacy" which the Registrant took in the Winter Session 1978-79. He advised that it was not a Residency Program.

Ms. Tsui's Evidence

Ms. Tsui is a Complaints Officer/Investigator at the College of Pharmacists and an inspector designated under the HPA. She is also a pharmacist registered with the College and has been a practicing pharmacist since 1999. She also has a law degree and is a member of the Law Society of British Columbia practicing with certain restrictions.

Ms. Tsui provided evidence by affidavit. In her first affidavit, Ms. Tsui confirmed the current status of the Registrant (as of November 30, 2015, Former Registrant), the current status of the Pharmacy (suspended since September 26, 2014) and that the Registrant is the sole director of the Corporation. Ms. Tsui advised that she participated in the March 2014 inspections. She was responsible for reviewing and investigating:

(i) the Professional Products Area of the Pharmacy;
(ii) the Professional Service Area of the Pharmacy;
(iii) the prescription pick-up drawer behind the dispensary counter in the Pharmacy;
(iv) any compliance packaging available in the Pharmacy, and
(v) the prescription filing system used by the Pharmacy.

Ms. Tsui explained that the term "Professional Products Area" refers to the area in the Pharmacy where drugs listed in Schedule III of the Drug Schedule Regulations (DSR) to PODSA are kept. Schedule III drugs are defined as "drugs which may be sold by a pharmacist to any person from the self-selection Professional Products Area of a licensed pharmacy." Use of the term "self-selection" means that the area of the pharmacy is accessible to the public. The term "Professional Service Area of a Pharmacy" refers to the area in a pharmacy where drugs listed in Schedule II of the DSR to PODSA are kept. Schedule II drugs are defined as "drugs which may be sold by a pharmacist on a non-prescription basis and which must be retained within the Professional Service Area of the pharmacy where there is no public access and no opportunity for patient self-selection".

Ms. Tsui stated that when she entered the Professional Products Area of the Pharmacy, she saw two shelving units, each with four sides, stocked with products with "Marigold Compounding" labels. This area was accessible to the public. She noted that many of the products listed plant materials such as calendula and aloe vera as ingredients. Plant materials like calendula and aloe vera are included in NHPR as Schedule I substances. No concentration or quantities of such ingredients were listed on the labels. She also observed various expired products on the shelves in the Professional Products Area. She also noticed in the "Professional Products Area" items with the product labels "Psoriagold" and "Scarline". The labels indicated that the product's ingredients contained "Coal Tar and Anthralin" and "Urea" respectively. All three drugs are listed in Schedule II: Urea is a Schedule II drug in topical

preparations in concentration of more than 25%, Coal Tar in concentration of more than 10% and Anthralin in any concentration. There were 15 containers of "Psoriagold" on the shelves and 10 containers of "Scarline". Neither of these products are commercially available and all had "Marigold Compounding" on the labels and no patient names. There were also at least 145 different products on the shelves in the Professional Products Area and approximately 5-10 containers of each product.

Ms. Tsui also examined the Professional Service Area which the public does not normally have access to. Ms. Tsui observed several shelves in the Professional Service Area that held many containers that had "Marigold Compounding and Natural Pharmacy" labels. Some of these labels listed ingredients (vitamins and minerals) which are included Natural Health Products under Schedule I of the NHP regulations (such as magnesium and Vitamin E). The labels did not list the concentration or quantities for any of the ingredients. She also noticed products with expired expiry dates or errors in the listing of its expiry date (Ms. Tsui first affidavit, paragraphs 37, 38, and 39). Ms. Tsui formed the opinion that the products were prepared on site, based on the number of products and their labelling. She also concluded that a patient-pharmacist relationship did not exist between the Registrant and any individual who would purchase these products as:

(i) the quantities of the product did not suggest that they had been compounded further to a particular prescription or prescriptions;

(ii) the labels did not include a patient name,

(iii) the products were available for purchase without a prescription; and

(iv) based on the layout of the Pharmacy, wherein the Professional Service Are is not visible from the Dispensary and that the Registrant appeared to spend most of his time in Dispensary and that there was a Pharmacy employee located in the Professional Service Area at the cash register, it appeared that a customer would likely be able to purchase these products without any pharmacist interaction.

Ms. Tsui also noted that on July 23, 2010, Health Canada published an advisory for unauthorized health products sold by Marigold Natural Pharmacy. The Health Canada Advisory included an information update which specified over 400 products from the Pharmacy which may pose specific risks to the health and safety of the public. Some of these same listed products i.e., L-lysine, 6 Warriors, Guaifenesin, Maggie Max were seized during the March 2014 inspection

Ms. Tsui also examined prescriptions contained in the Pharmacy's prescription pick-up drawer. The medications were either inside a paper bag or black plastic bag. There were ten processed prescriptions in the pick-up drawer. Five of the ten prescriptions showed dispensing dates that were more than thirty day after the date of the original entry of the prescription information in PharmaNet. The dispensing dates were October 24, 2013; October 23, 2013; January 16, 2014; October 16, 2013; and August 16, 2013. In addition, one of the labels did not identify quantity or strength of the included

medication. Under Section 21(5) of the PODSA by-laws, any drug that is not released to the patient must be reversed in the PharmaNet database no later than 30 days from the recorded dispensing date and the reason for reversal must be recorded. This is done to facilitate accurate and current patient drug information for authorized Pharmanet users.

Ms. Tsui also examined the prescription filing system being used by the Registrant. She found the system to be disorganized with prescriptions located in several places within the Pharmacy, not filed in any order, and with narcotic and non-narcotic prescriptions being filed together (not separated as required by Professional Practice Policy #12). The Registrant also advised that some prescription records may be at his offsite office. The prescriptions were not organized by date, sequential prescription number or transaction number. PPP-12, Prescription Hard Copy File Coding System, Section 7 requires that all prescription hard copies must be readily available, regardless of storage site for a period of three years.

Ms. Tsui seized 146 products from the Professional Products Area and 63 products from the Professional Service Area. Relying on information contained on the labels, Ms. Tsui concluded that 142 of the 146 products from the Professional Products Area listed ingredients classified as NHP and 61 of 63 products from the Professional Service Area contained NHP ingredients. Seven of the products listed ingredients that, in certain concentration, are scheduled under the Drug Schedules Regulation of PODSA. The label did not indicate the concentration level of these ingredients. Ms. Tsui estimated that there were approximately 2000 manufactured products in the Professional Products Area and the Professional Products Area and the Professional Service Area of the Pharmacy on March 4, 2014.

Ms. Tsui also prepared two PharmaNet reports for the Registrant; one from the period January 1, 2013 to December 31, 2013 and the other from January 1, 2014 to September 26, 2014. These reports show the products dispensed by the Registrant during this time period. The reports also indicate the patient's name, the prescribing physician or pharmacist, the product prescribed and the product provided to the patient.

Polly Graves' Evidence

Ms. Graves is a licensed pharmacist and a Complaints Resolution Investigator with the College and an inspector designated under the HPA. Ms. Graves attended both the March 2014 and September 2014 inspections. However, Ms. Graves had also previously attended an inspection of the Pharmacy in July 2013. A number of deficiencies were identified at the July 2013 inspection and were brought to the Registrant's and Pharmacy's attention in an "Inspection Reply Form". Ms. Graves gave evidence (by affidavit) respecting the previous inspection and the deficiencies. Twenty-two matters were identified in the Inspection Reply Form including concerns about having a proper refrigerator (one which meets

PPP68) with a proper memory thermometer, properly maintained prescription logs, removal of expired products from shelves, removal of new prescriptions which were not picked up within thirty days, proper labelling information on products (dispensing date, strength of product, quantity), proper compounding logs, and a proper "hood" for preparing sterile preparations (ISO5). A complete list is found at paragraph 6, page 3 of Ms. Graves affidavit. The Registrant, on August 9, 2013, certified to the College that the corrections identified in the "Inspection Reply Form" were made and that the deficiencies identified will not be present at subsequent site visits. Correspondence between the College and the Registrant and Pharmacy continued through the fall and winter of 2013 wherein the College sought additional information to confirm that the deficiencies had been properly addressed and the Registrant provided responses.

Ms. Graves attended the March 2014 Inspection and was responsible for reviewing and inspecting the following issues:

(i) documentation for prescriptions where the Registrant was identified as the prescriber;

(ii) inventory management including expired products in the dispensary and dispensary product labels; and

(iii) narcotic reconciliations.

As part of Ms. Graves' investigation and inspection, Ms. Graves, using PharmaNet Records from January 1, 2013 to December 31, 2013, identified 84 prescriptions for compounded and Schedule 1 medications where the Registrant used his own name as the prescriber. At the March 2014 Inspection, she specifically searched for the original prescriptions for these 84 transactions. She examined the filed prescription folders for the original prescription and any accompanying documentation, such as compounding logs or adaptation documents. She located records for only fourteen, nine from the on-site investigation and five in the records seized by the College. She reviewed all the folders in the prescription filing cabinets. She also located other unlabeled folders containing 2011 and 2012 prescriptions. She noted that prescription records were not filed chronologically or by prescription or transaction number, and that narcotic prescriptions were not filed separately from regular prescriptions. Also, some original narcotic prescriptions were not filed but were in a binder labelled "Marigold Patient Logs". The Registrant was requested to provide the missing documentation for the seventy prescriptions that Ms. Graves was unable to locate. The Registrant did not respond to that request.

Of the fourteen prescriptions that Ms. Graves could locate she had concerns relating to the labels (strength of active ingredients, expiry dates), to proper records respecting a change in the prescriber (from a physician to the Registrant), and to proper compounding logs.

Ms. Graves stated at paragraph 66, pages 14-15 of her affidavit:

> "It was difficult for me to locate original prescriptions records and accompanying documentation, due to a lack of organization and order in the Pharmacy. The disorganization and lack of order made it difficult for me to determine why a prescription was filled, whether an original prescription

existed, what the clinical rationale was for providing a medication, what medication or compound was dispensed, whether a medication or compound was provided as an adaptation or an emergency fill, and the specifics of the compounds that were presumed to be prepared for these prescriptions. I could not find documentation for 70 prescriptions."

Ms. Graves, at the March 2014 Inspection, also determined from a conversation with the Registrant that PPP-65 Narcotic Counts and Reconciliations which requires narcotic counts and reconciliations every three months was not being complied with. The last narcotic count and reconciliation was done in response to the previous inspection in July 2013. The failure to maintain proper narcotic documentation made it difficult to determine what was actually occurring with the narcotics in the possession of the Registrant and the Pharmacy. Ms. Graves also provided evidence respecting inappropriate expiry dates (referring to Policy 51 that states that expiration dates of the compounded product is based on known stability data). Ms. Graves was unable to locate information on expiry dates or any stability data for raw materials used in compounded products. As a result, she was of the view that at least ten of the Pharmacy's compounded products had expiry dates excessively longer than the standard for non-sterile compounded products. She also provided examples of compounded products located in the Dispensary area which had expiry dates beyond six months (some up to five years) when the recommended maximum beyond use dates for non-sterile non-aqueous compounded formulations is at most six months. She also found numerous instances of products in the Dispensary that lacked complete label information. Ms. Graves advised that the minimum pharmacy practice standards require drugs to be labelled, whether stored in the original container, repackaged or compounded. Ms. Graves found drug products with labels missing some of the following: expiry dates, lot numbers, the strength of active ingredients, beyond-use dates (for compounded products), and preparation dates (compounded products).

Ms. Graves also attended the September 26, 2014 inspection and seized several items from the Dispensary shelves.

Ms. Graves summarized the observed infraction of the March 2014 Inspection in her Investigation Report at pages 49 and 50 (Exhibit F to her affidavit). She stated:

"In conclusion, the following is a summary of infractions observed from the inspection:

Prescription Documentation:

- The prescription records were not filled chronologically or by Rx or Tx number.
- Narcotic prescriptions were not filed separately.
- Prescription file folders were not labeled or insufficiently labeled.
- Compound log sheets were attached for 3 of 7 compounded documentation.
- 14 records were located out of the 84 prescriptions searched for.
- Prescription documentations was not found for 70 prescriptions.
- Non-compliance with prescription filing regulations was identified as a concern in previous inspections at Marigold Pharmacy.
- The Registrant had signed statements confirming that these deficiencies were no longer present in his pharmacy.

- These deficiencies were again identified as an area of concern during the March 2014 Investigation.

Narcotic Counts and Reconciliations

- 12 of 13 narcotic counts and reconciliations were not done, between September 2011 and September 2014.
- In this time, the Registrant only conducted 1 count after being found deficient during the 2013 college inspection.
- The Registrant was non-compliant with PPP-65 Narcotic Counts and Reconciliations.
- Counts and reconciliations had not been done every 3 months and had not included narcotic compounds.

Inventory management – Expired Stock, Labelling, Storage

- There were 41 expired or inadequately labelled items.
- 9 compounded products had inappropriately long expiry dates.
- 1 compounded product did not have an expiry date.
- 12 products had issues with missing required label information.
- 1 product was stored contrary to its labelled storage requirements.
- Inventory management of expired stock, meeting the minimum labelling requirements, and storage were identified as discrepancies and patient safety concerns during previous inspections of Marigold Pharmacy.
- These issues had previously been identified and brought to the Registrant's attention.
- The Registrant had signed statements to the effect that these concerns had been addressed and would not be present at future inspections.
- These continued to be areas of concern identified during this inspection.

Overall, the principal concern arising out of my observations from this inspection is that the issues have been ongoing and remain even after inspections, suspensions, consent agreements, and signed declarations from the Registrant stating they would not occur again.
There is a concern that the Registrant poses a threat to public safety because he has continued to practice in a manner in that does not meet the minimum Standards of Practice of Pharmacy, in several practice areas."

Jonathan Lau's Evidence

Jonathan Lau is a Compliance Officer at the College. In 2014, he was an Inspector/Practice Consultant with the College and attended the March 2014 Inspections of the Pharmacy. He was paired with Ms. Jeon and tasked, along with Ms. Jeon, with reviewing the following areas of practice at the Pharmacy:

(i) the Compounding Room and compounding practices; and

(ii) the Manufacturing Area

Mr. Lau was also responsible for reviewing:

(i) a small room between the Compounding Room and the Dispensary. This room was referred to as the Excess Room;

(ii) a small room off the Compounding Room where a laminar flow hood was located (the "PEC" Compounding Room"), and

(iii) the compounding equipment located in the Compounding Room and the PEC Compounding room

Mr. Lau advised that the Excess Room was packed with cardboard boxes and plastic bags. He located a small refrigerator or "bar fridge" which had medications, including insulin vials and vaccines stored in it. The bar fridge had a displayed temperature of 12.6 degrees Celsius. Mr. Lau asked the Registrant for a temperature log for the bar fridge. He did not provide one to Mr. Lau.

Mr. Lau also inspected the Compounding Room. He saw semi-finished compounded products on the work bench. There were also many source materials and finished compounded products.

Mr. Lau also inspected the PEC Compounding Room. From his observations, Mr. Lau concluded that the PEC Compounding Room was intended to be used as a sterile compounding room. This was because the PEC Compounding Room contained a laminar flow hood. A laminar flow hood is used for the preparation of compounded products that require a sterile environment during compounding. The College, (through the Guidelines to Pharmacy Compounding PPP-64) has adopted the National Association of Pharmacy Regulatory Authority (NAPRA) Guidelines to Pharmacy Compounding, October 2006 which require sterility testing to be done according to a clearly defined standard such as USP and that "standards for the operation of clean rooms and the preparation of sterile products should be documented in accordance with a recognized source (e.g. Canadian Society of Hospital Pharmacists)". The United States Pharmacopeial Convention establishes primary standards for ensuring quality in pharmaceutical compounding, including USP 797. USP 797 speaks to having primary and secondary engineering controls such as the laminar flow hood certified and tested by a qualified individual no less than every six months. The Registrant advised Mr. Lau that the laminar flow hood was certified only once, when it was installed. The Registrant also advised Mr. Lau that the laminar flow hood has been in the Pharmacy for longer than six months and no certification or testing by a qualified individual had been scheduled since it was installed.

USP 797 also specifies International Organization for Standardization (ISO) standards which would apply to certain areas of the PEC Compounding Room, in particular ISO Class 5 and ISO Class 7 standards. USP 797 requires the hood in the room in which sterile products are compounded to provide an ISO Class 5 Environment. Mr. Lau asked the Registrant to produce documents to show that the laminar hood met ISO Class 5 standards. The Registrant was unable to do so. The PEC Compounding Room is also required to meet ISO Class 7 standards. Again, the Registrant was unable to produce any documents to show that the PEC Compounding Room met ISO Class 7 standards.

The Registrant also advised Mr. Lau that the PEC Compounding Room was enclosed with no ventilation to the outdoors. It also lacked temperature, airflow or air pressure controls or monitors.

Mr. Lau also inquired if there was ante-room or ante-area that met ISO Class 8 standards. The Registrant advised that there was no ante-room or ante-area that met ISO Class 8 standards. The Registrant also did not provide Mr. Lau with any other documentation to show that the PEC Compounding Room followed a different standard from the USP standard.

Mr. Lau and Ms. Jeon seized 54 product samples during the March 2014 Inspection. They determined that 14 of them included ingredients falling into Schedules 1, 1A, II, III or IV of the DSR under PODSA. They were of the opinion that the 14 products were likely manufactured at the Pharmacy based, in part on the bulk quantities of the products that were available, the labelling of the products and the lack of patient-specific information associated with the products.

Mr. Lau and Ms. Jeon were only able to locate compounding records for some of the 54 products. Of the records they could locate, 26 of them were missing information required by NAPRA's Guidelines to Pharmacy Compounding such as:

(i) the name, lot number and expiry date of the raw materials,

(ii) the quantity required and quantity actually weighed,

(iii) the date of preparation and expiry for the product,

(iv) the initials or signature of the compounder and/or pharmacist responsible for the preparation and checking of the product,

(v) the written formula used,

(vi) the records of stepwise operating and processing instructions, and

(vii) any related training records.

Eighteen of the product samples had labels that either had an inappropriate beyond-use date and/or were missing one or more of the following:

(i) a list of active ingredients,

(ii) a prescription or identification number of the compounded product, and

(iii) an estimate beyond-use date printed at the end of the dosage duration.

Mr. Lau also advised that of the 54 products seized, 34 appeared to be Natural Health Product manufactured by the Pharmacy. The labels indicated that these items were produced by mixing unscheduled drugs and herbal products, such as grapefruit seed and magnesium chloride. The labels and compounding records did not include any indication that the products were prepared for a specific patient.

Lastly, Mr. Lau advised that he found expired source material and final products in both the Compounding Room and the Manufacturing Area. Of the 54 samples seized, two of them contained expired ingredients or were expired themselves (one expired March 2013 and the other August 2013).

Mr. Lau attached as an Exhibit to his affidavit, his Inspection Report (Exhibit 13). Mr. Lau stated in his report that the numerous deficiencies identified by Ms. Polly Graves in her inspection of the Pharmacy in July 2013 were again observed in Mr. Lau's inspection on March 4, 2014. Mr. Lau summarized his report as follows:

1. The Registrant continued to manufacture scheduled drugs without a Drug Establishment License and natural health products without a Site License, in violation of Health Canada *Policy on Manufacturing and Compounding Drug Products in Canada* and Health Canada *Natural Health Products Regulations*.
2. The compounding conditions and equipment used did not comply with PPP-64 *Guidelines to Pharmacy Compounding* and NAPRA *Guidelines to Pharmacy Compounding*. Environmental controls continued to be absent, and compounding equipment like the hood was uncertified. The medication refrigerator was of the wrong type and its temperature was beyond the acceptable range.
3. Compounded and repackaged products were not labelled according to standards of PPP-64 and HPA Bylaws respectively, with many vital information, like the beyond-use-date of the final product or the complete list of active ingredients missing; this was also identified in the previous investigator's report.
4. Documentation of activities pertaining to compounding was seriously lacking. Refrigerator temperature logs were absent; compounding logs were either incomplete or non-existent, and training records for himself and his compounding staff were not available.
5. Expired raw materials were still used for compounding and manufacturing, in violation of *PODSA Bylaws Sale and Disposal of Drugs*.
6. Uncertified raw materials were still used for compounding and manufacturing, in violation of *PODSA Bylaws Sale and Disposal of Drugs*.
7. The Registrant has not been able to produce any records of training for himself and his staff participated in compounding.
8. Prescription filing did not comply with PPP-12 *Prescription Hard Copy File Coding System*.

He also concluded that the Registrant was in breach of the following undertakings from the Consent Agreement:

1. To obtain a Canadian Drug Establishment License and a Site License.

2. To comply with the Guidelines to Pharmacy Compounding from NAPRA (and therefore PPP-64).

3. To comply with the Regulations when dispensing selling, manufacturing and compounding drugs and natural products.

Mr. Lau concluded his Inspection Report by expressing his "grave concerns for public safety based upon the fact that scheduled drugs were compounded without the proper licensure, facility and equipment, and the fact that expired products were used in compounding and sometimes sold to patients directly". Documentation, in way of refrigerator temperature logs, compounding logs and training records were either incomplete or non-existent.

Ms. Deborah Rees-Lee's Evidence

Ms. Rees-Lee was a Complaint Resolution Officer with the College from 2013 to 2017. She was appointed as inspector for the purpose of participating in an inspection of the practice of the Registrant at the Pharmacy. She attended the March 2014 and September 2014 inspections.

At the March 2014 Inspection, Ms. Rees-Lee was responsible along with Ms. Tsui to review the expiry dates indicated on product labels and also those containers that Ms. Tsui identified as containing drugs listed in Schedule II of the DSR to PODSA in the Professional Product Area (PPA) of the Pharmacy (over the counter, public access, front store area) and the Professional Services Area (behind the front service counter not accessible to the public). Ms. Rees-Lee was also responsible to interview the Registrant on his responsibilities as pharmacy manager of the Pharmacy.

Ms. Rees-Lee identified products in the PPA with expired dates on the product label or missing expiry dates on the product label. There also were 40 containers of an ointment that had a confusing expiry date- 2/ 7/2014. It was unclear if this referred to February 7, 2014 or July 2, 2014. If the former, the product had expired. There were also two products containing Schedule II ingredients of unknown concentrations. The labels of these products were not in compliance with either the FDR or the NHPR and if the product contained the Schedule II ingredients at the concentration stated in the FDR, their availability in the PPA was not in compliance with PODSA Drug Schedules Regulation. These comment and observations are consistent with Ms. Tsui's evidence.

In respect of Ms. Rees-Lees' responsibility to interview the Registrant on his responsibilities as manager of the Pharmacy, Ms. Rees-Lee advised that she compiled a list of 23 legislative requirements and standards based on the responsibilities of Pharmacy Managers, Owners and Directors as described in ss. 3 and 10 of the Bylaws to PODSA. Ms. Rees-Lee specifically enquired about the Pharmacy's Policy and Procedures Manual. Ms. Rees-Lee found the Marigold Policy and Procedures Manual to be inadequate and contrary to Bylaw S.10(a) of PODSA. There were a number of areas of deficiencies including: the lack of a Policy on Drug Recall; no policy or process for "reporting, documenting and following up on known, alleged and suspected errors incidents and discrepancies related to the customer or patient; no adequate policy on "reasonable security arrangements of unauthorized access, collection, sue, disclosure or disposal of personal information kept on pharmacy premises; no policy on appropriate security and storage of all Schedule I, II and III drugs; and no policy or record log pertaining to the purchase and receipt of controlled drug substances.

Ms. Rees-Lee also attended the September 2014 inspection. She assisted Ms. Jeon in the inspection of the Compounding Room and the seizure of items from the Compounding Room. She also assisted Ms. Graves and Mr. Budd in the seizure of drugs and other items from the Dispensary.

Ms. Lynn Pollock's Evidence

Ms. Pollock is a Registrant with the College and has acted as a practice auditor with the Professional Development and Assessment Program of the College. She was appointed an inspector for the purposes of an inspection of the Pharmacy on March 4, 2014. She attended the Pharmacy on March 4, 2014 and was responsible for observing the Registrant in his day-to-day practice of pharmacy. She was to assess whether the Registrant met the standards of a reasonably competent pharmacist as per the applicable Legislation, the bylaws of the College and the ethics and professional practices of the profession. She used the Framework of Professional Practice which describes the standards the College uses to assess quality of pharmacy practice. She also used the College's Detailed Code of Ethics Standards. As part of her responsibilities at the inspection site, she:

(i) conducted a review of prescriptions being dispensed at the Pharmacy to ensure that authorized prescribers were noted,

(ii) checked that medications dispersed were within the applicable date for use, and

(iii) reviewed the pharmaceutical care provided by the Registrant to patients including patient assessment, drug and non-drug recommendation made for patients, directions for use provided for prescription and non-prescription product, precautions provided and referrals made to other health care providers.

Ms. Pollock observed the Registrant and his interactions with patients, staff and other health professionals. She also observed his dispensing activities. She reviewed three consult files and several prescription and computer files.

Ms. Pollock identified a number of concerns respecting the Registrant's practice. She stated in her "Summary of Observations from the Investigation" that:

"What is of concern to me in this case, in addition to the specific issues noted in the report, are the number of risks that I assessed in situations which occurred and the breadth of practice infractions that did not meet current standards of pharmacy practice."

She states at page 13 of her Inspection Report that "I am concerned that the Registrant's practice presents a potential risk to public safety".

In her affidavit, Ms. Pollock identified specific concerns respecting confidentiality of patient personal information, failure to maintain complete records in the patients consult report (failure to record all patient information, reliance upon memory), failure to advise patient of risk arising from use of certain medications, no follow up with the patient's physician to discuss the patient's condition or risk, failure to maintain a proper filing system for prescriptions, improper expiry dates, lack of proper detail on labels (use of weak/strong rather than actual strength of dosage), failure to send his manufactured products for assay or stability testing, and the Registrant's process for human placental encapsulation.

Ms. Pollock sought additional information from the Registrant on March 18, 2014.She received a response on March 27, 2014 and sought additional information on April 28, 2014. No response was received from the Registrant to the April 28, 2014 request for additional information.

Although the Registrant did not attend the hearing, he had provided some responses to enquiries arising out of the July 9, 2013 inspection and March 4, 2014 Inspection. Arising from the July 2013 inspection, the Registrant was requested to provide information about his narcotic count and reconciliation process and for a description of his quality assurance process for determining products are sterile, including any documentation he kept (Letter of September 27, 2013 to the Registrant, from Donna Nikkel of the College, Exhibit B of Ms. Graves' affidavit). The Registrant, in his response, dated October 11, 2013 advised in response to the question respecting "quality assurance process for determining products are sterile" stated:

> "Cost of certification for the sterile room and upgrades to the venting system of the building is prohibitive at this time and the Pharmacy cannot afford to incur the expenses of the certification and building upgrades…
>
> Therefore, it has been decided to curtail the preparation of any sterile products".
>
> (Exhibit C of the affidavit of Polly Graves, at page 21)

The Registrant did initially respond to a request from Ms. Pollock for information arising from the March 2014 Inspection (email from Ms. Jeon to Registrant, March 18, 2014; response to Ms. Jeon, letter of March 26, 2014 (see Exhibit 3 and 4 of Ms. Pollock's affidavit)). However, a request for additional information respecting "placental encapsulation", "patient consult", "patient documentation" and "titration of a prescription" dated April 28, 2014 from Ms. Pollock went unanswered.

Legislation, Bylaws and Policies

The relevant legislation that applies to pharmacists and pharmacies includes both provincial and federal statutes and regulations. The Health Professions Act establishes the College of Pharmacists of British Columbia. In addition to certain general provision in the HPA (superintend the practice of the profession, govern registrants, and establish, monitor and enforce standards of practice and standards of professional ethics), the HPA also establishes certain objectives unique to the College including: (1) to establish terms and conditions of sale for drugs and devices and (2) to ensure the public is protected from the unauthorized or inappropriate sale of drugs and devices. In addition, the college is to superintend the operation of pharmacies. The Pharmacy Operations and Drug Scheduling Act (PODSA) authorizes the College to regulate pharmacies and their operation. It provides for the licensing of pharmacies by the College and their regulation in relation to their operation, ownership and

management. The Drug Schedules Regulation (DSR), enacted by the Board under PODSA, sets out a list of drugs that must be sold through a licensed pharmacy and defines the conditions under which those drugs may be sold through a licensed pharmacy.

Federal Legislation also classifies and licenses drugs and natural health products (NHPs) and established standards for their handling, sale and processing. This includes the Food and Drug Act, the Controlled Drug and Substances Act, the Food and Drugs Regulations, the Natural Health Products Regulation, The Marihuana for Medical Purposes Regulations, and the Narcotic Control Regulations.

Lastly, the College has created Professional Practice Policies (PPP) that create and explain the standards to which registrants must adhere to. These include:

(a) PPP-12 Prescription Hard Copy File Coding System
(b) PPP-58 Medication Management (Adapting a Prescription)
(c) PPP-64 Guidelines to Pharmacy Compounding
(d) PPP-65 Narcotic Counts and Reconciliations, and
(e) PPP-68 Cold Chain Management of Biologicals

PPP-64 adopts the National Association of Pharmacy Regulatory Authorities Guidelines to Pharmacy Compounding 2006 (the "NAPRA Guidelines") as the standard of practice for registrants in relation to compounding. PPP-68 adopts the BC Centre For Disease Control's Communicable Disease Control Immunization Program: Section VI – Management of Biologicals as the standard of practice for registrants in relation to cold chain management of biologicals.

Analysis

The Citation set out 21 allegations and provides 14 pages of particulars containing 31 paragraphs many with multiple alleged instances of breaches of Acts, Regulations or PPPs. The College asserts that the Citation contains allegations pertaining to 7 broad areas of conduct:

1. that the Registrant and Pharmacy engaged in the manufacture of drugs and NHPs without the licenses required under Federal Legislation and without adhering to the standards set out in the Legislation.

2. that the Registrant, or persons practicing under the supervision of the Registrant, engaged in pharmacy practice that did not meet the applicable standards in a number of respects.

3. that the Registrant and Pharmacy engaged in the manufacture, storage and dispensing of marihuana without the license required by the MMPR and contrary to the requirements of the MMPR and NCR.

4. the Registrant engaged in the encapsulating of human placenta when that substance was not recognized under the FDA.

5. the Registrant failed to cooperate with the College's investigation of his practice,

6. the Registrant misrepresented his educational qualifications and the capabilities of the Pharmacy in marketing related to practices at the Pharmacy, and

7. the Registrant was in breach of the Consent Agreement entered into between the Registrant and the College and failed to comply with the Inspection Reply Form.

Several of the allegations are in the alternative (Allegation (7) and (8), Allegation (10 and (11), Allegation (14) and (15), Allegation (16) and (17), Allegation (18) and (19)). Further, some of the allegations are more explicit examples of the contravention of the relevant statutory provisions. For example, the allegations respecting cannabis are examples of alleged breaches of the MMPR, and the allegations respecting compounding and manufacturing are examples of the failure to comply with the NHPR and the FDR.

These allegations, although specific to cannabis or the compounding/manufacturing of natural health products/drugs, are in fact captured in the first general allegations of breaches of various statutes, regulations, policies and standards. Accordingly, the Panel has chosen to focus on Allegations 1, 2, 3, 4, 9, 20 and 21.

Allegations 4 and 9

Failure to Comply with the Terms of the Consent Agreement of September 2011 Failure to Correct Deficiencies in the Inspection Reply Form Arising from the July 2013 Inspection

The Inquiry Committee suspended the Registrant's registration and the Pharmacy license in June 2010. This action arose out of a complaint received by the College in May 2010. In September 2011, the Registrant signed a Consent Agreement which included undertakings from the Registrant, both on behalf of himself and the Pharmacy, aimed at ending the practice deficiencies that were of concern to the Inquiry Committee. In the Consent Agreement, the Registrant and the Pharmacy undertook to obtain the appropriate Canadian Drug Establishment License to manufacture drugs and a Site License to manufacture natural health products as required under the FDA, FDR, and NHPR before engaging in the manufacturing of any drug product or natural health product. Further, the Registrant and the Pharmacy agreed to comply with the Guidelines to Pharmacy Compounding (2006). The Registrant further undertook to become familiar with and comply with the College's professional standards with specific reference to compounding and prescribing practices. Thus, as a result of the earlier investigation and consent agreement, the Registrant had been put on notice of the need to and importance of complying with the legislative regulating regime and policies and procedures set out by the College. As outlined in the discussions under the other headings, the Registrant failed to fulfil his

undertakings with respect to manufacturing or compounding as well as complying with the requisite policies and procedures.

With respect to Allegation 9, the failure of the Registrant to correct the deficiencies in pharmacy practice at the Pharmacy as outlined in the Inspection Reply Form is detailed in Ms. Graves' evidence. The Registrant by signing the Inspection Reply Form represented that the deficiencies identified in the July 2013 inspection had been corrected. The Registrant signed the Inspection Reply Form in August 2013 but the subsequent inspections in March and September 2014 disclosed that the same concerns present in July 2013 regarding refrigeration, presence of expired products, removal of prescriptions not picked up within 30 days, proper labelling information, proper prescription filing, and sterility issues were present in the March and/or September inspections.

Allegations 1, 2, and 3

Engaging in the Practice of Pharmacy in Contravention of the Health Professions Act, The Pharmacy Operations and Drug Scheduling Act, The Controlled Drug and Substances Act, The Food and Drugs Act, including Regulations Under Those Acts, The Colleges Professional Practice Policies and Generally Accepted Standards of Pharmacy Practice

A. Failure to Obtain Drug Establishment License and Site License

Under the FDR, a person must hold an Establishment License from Health Canada before fabricating, packaging, labeling, and distributing a drug (FDR, s. C. 01A.004(1)). Fabricate is defined as "to prepare and preserve a drug for the purposes of sale". However, the requirement to obtain an Establishment License does not apply to a pharmacist "compounding, pursuant to a prescription, drug that is not commercially available in Canada." Further, no person can manufacture, package, label or import natural health products (NHPs) unless they hold a Site License from Health Canada. The NHPR defines a NHP as a substance set out in Schedule 1 of the NHPR and includes a range of vitamins, an amino acid, an essential fatty acid, a mineral, a probiotic or a synthetic duplicate of a listed vitamin, amino acid or fatty acid.

The College in PPP-64, Guidelines to Pharmacy Compounding has adopted a distinction between the activities of compounding and manufacturing.

Compounding – Pharmaceutical preparation of components into drug products that:

- are considered to be within the professional practice of pharmacy, regulated by provincial regulatory authorities in accordance with guidelines and standards that ensure quality and safety of pharmaceuticals.

- involve a relationship that can be demonstrated to exist between a patient and/or a regulated health care professional or a practitioner.

- do not circumvent regulatory requirements including the Food and Drug Act, the Food and Drug Act Regulations, the national Drug Schedules, or Intellectual Property Legislation.

- provide a customized therapeutic solution to improve patient care without duplicating a commercially available approved product.

Manufacturing – Preparation of Products:

- are subject to all the appropriate divisions and sections of the Food and Drug Act and Regulations, including all applicable standards and guidelines.

- require a Drug Identification Number (DIN) and/or Notice of Compliance (NOC) to be sold in Canada.

- are produced independently of the demonstrated regulated health care professional – patient relationship or valid pharmacist –veterinarian-client-patient relationship.

- are required to obtain an Establishment License and meet the appropriate section of Division 2 Good Manufacturing Practices.

Further, Health Canada's Policy on Manufacturing and Compounding Drug Products, POL-0051 includes the following:

Factors to be considered when assessing whether an activity is compounding:

(a) Healthcare professional who provide compounding related services and products to patients/clients must be able to demonstrate that a patient-healthcare professional relationship exists.

(f) The compounded product must provide a customized therapeutic solution to improve patient a care without duplicating an approved drug product.

An activity will be considered manufacturing in the following circumstances:

(a) Healthcare professional who cannot demonstrate that a patient-healthcare professional relationship exists.

(b) Producing an identical product that is already commercially available, unless there is a shortage.

(d) Healthcare professional who produce products intended for distribution or sale outside the demonstrated patient-healthcare professional relationship.

(e) Producing products made in such scale, time and frequency to fall outside of a patient-healthcare professional relationship.

(h) Repackaging commercially available drugs in finished dosage form outside the normal dispensing activities within the practice of pharmacy.

It is clear from the evidence that the Registrant had been made aware of the requirements for the obtaining of the appropriate Establishment and Site Licenses since the date of Consent Agreement in

September 2011. He acknowledged to Ms. Jeon during the March 2014 Inspection, that he had not obtained either license but was in the process of doing so and that there was a grace period while he was waiting during which he could manufacture drugs and NHPs without the requisite license. Ms. Seeling advised that no such grace period exists. She also advised that no Establishment or Site License had been granted to the Registrant or the Pharmacy.

The Registrant also acknowledged that he did manufacture drugs and natural health products. During the March 2014 Inspection, he acknowledged to Ms. Jeon, when asked, that he manufactured both drugs and NHPs in the Compounding Room of the Pharmacy. Again, at the September 2014 inspection, Ms. Jeon asked the Registrant if the NHPs sealed with "Marigold Compounding and Natural Pharmacy" labels located in the Second Manufacturing Room of the Pharmacy were manufactured on site at the Pharmacy. The Registrant said yes.

The Registrant's acknowledgement that manufacturing of drugs and NHPs was occurring at the pharmacy is consistent with the evidence in relation to the items seized during the March 2014 and September 2014 inspections. Numerous items were seized by both Ms. Jeon and Mr. Lau and by Ms. Tsui and Ms. Rees-Lee during the March 2014 Inspection. The labels indicated that they were produced at the Pharmacy (i.e. "Marigold Compounding and Natural Pharmacy" or "Marigold Formula or "custom formulation"). They were available in large quantities (multiple containers, compounding logs indicated large quantities prepared). These labels lacked any patient specific information and often included a fixed sale price.

During the September 2014 inspection, approximately 6000 containers of drugs and NHPs were seized from the Pharmacy. The College returned some products but approximately 2000 containers were retained. Many of these items had the Pharmacy name on the labels, lacked any patient names or other identifying information specific to a patient and were available in bulk quantities.

The evidence that the Registrant and the Pharmacy were engaged in the manufacture of drugs and NHPs is overwhelming. It is also clear that the Registrant, although aware of the need to obtain the appropriate Establishment and Site Licenses, chose to proceed without the said licenses in violation of the Consent Agreement of 2011, the Inspection Reply Form of 2013 and with the knowledge that he was in breach of the FDR and NHPR. As such Allegations 4 (Failure to comply with the terms of the consent agreement) and 9 (Providing untrue information in the Inspection Reply Form) are proved as are the violations of the FDR and NHPR.

B. Substandard Pharmacy Practices

It is alleged by the College that the Registrant failed to comply with or meet a number of the College's Professional Practice Policies (PPPs) and standards and also did not comply with the College's Bylaws. Some of the alleged breaches include:

(a) failure to properly file prescriptions (PPP-12 and PODSA Bylaw section 8)
(b) failure to conduct timely and proper narcotic inventory control (PPP-65)
(c) failure to follow proper Cold Chain Management of Biologicals (PPP-68)
(d) failure to maintain required records for products compounded in the Pharmacy (PPP-64)
(e) failure to label drugs and NHPs properly (NAPRA Guidelines and Schedule F of Bylaws)
(f) failure to maintain sterile compounding/manufacturing equipment and facilities, and
(g) engaged in inappropriate and improper prescribing practices.

(a)Prescription not properly filed

Section 8 of the PODSA Bylaws require pharmacists to retain all prescriptions for a period of not less than three years. Section 2 of PPP-12 (Prescription Hard Copy File Coding System) provides that "Prescription files must be organized chronologically by date and sequentially by prescription number or transaction number". Further, Section 5 requires narcotic prescriptions to be filed separately from regular prescriptions.

The Registrant was aware of the requirement to file all prescriptions chronologically by date and prescription number, having signed the Investigation Reply Form in August 2013 in which he undertook to file prescriptions chronologically and by prescription number. Ms. Graves, in her affidavit, stated that at the March 14 Inspection, she attempted to locate 84 prescription transactions that were dispensed through PharmaNet using the Registrant's name as the prescriber from January 1, 2013 to December 31, 2013. She was unable to locate 70 out of the 84 prescriptions. In the process of looking through the filing cabinets containing the Pharmacy's prescriptions, she observed that the prescription records were not filed chronologically or by prescription or transaction number, nor were the narcotic prescriptions filed separately from the regular prescriptions.

Ms. Tsui also reviewed the filing cabinet containing the Pharmacy's prescriptions. Her evidence was similar to Ms. Graves. There was no discernable order to how the prescriptions were filed. The evidence was that there was a low prescription volume at the Pharmacy (the Registrant stated that the Pharmacy handles about 16-25 prescriptions per day). The volume was such that a proper filing procedure could have been adopted without any difficulty.

The evidence clearly demonstrates that section 8 of the PODSA Bylaws and PPP-12 were not complied with.

(b)Narcotic Inventory Control

Under PPP-65 (Narcotic Count and Reconciliations), the pharmacy manager must ensure that narcotic counts and reconciliations are completed for the pharmacy. A narcotic count and reconciliation consists of four parts: perpetual inventory, physical inventory count, reconciliation and proper

documentation. It must be completed at a minimum every three months and include active inventory, compounded mixtures and expired inventory. A separate perpetual inventory is required for each narcotic drug. The date and signature of the person who completed the count and the date and signature of the responsible pharmacist must be documented and the documentation kept in chronological order in a separate and dedicated record that is retained for three years.

In August 2013, the Registrant undertook to do a complete narcotic count, according to Ms. Graves' affidavit. In response to a request from the College in September 2013, the Respondent provided in October 2013 a two-page report entitled "Narcotic and Controlled Drug Audit August 7, 2013". The report raised a number of questions. Ms. Graves requested additional information. The report did not provide a count of "expired inventory", did not identify who performed the count, was not verified and signed off by the pharmacy manager. The Registrant provided further details indicating that expired inventory was not included in the count contrary to the terms of the Policy.

Upon closer examination of the Narcotic and Controlled Drug Audit from Aug 7, 2013, it is noted that Supeudol 10mg, MS-IR 5mg, Ratio Lenoltec #3, and Teva Methylphidate ER 36mg are not listed in the audit. In the case of Supeudol 10mg, P/Care records from two months prior to the Aug 7/2013(date noted on the audit), indicate that this drug was dispensed on four separate occasions for 84 tablets per prescription for the same patient. The stock bottle quantity is 100 tablets and there should be at the very least a Supeudol entry in the audit and in all likelihood an inventory count. P/Net records also show the following entries; 20 x MS-IR 5mg on Apr 29/13, 30 x Ratio Lenoltec #3 on May 23/13 and 30 x Teva Methylphidate ER 36mg on Jul 12/13 yet these drugs are not listed in the audit and since these quantities do not match stock bottle sizes, it would be an expectation of remaining inventory.

Other discrepancies appear with Endocet, P/Net records from Mar 21/13 show 8 transactions for 112 tablets each yet the audit shows zero inventory count and system count and shows they are expired. P/Net records also show 90 x M-Eslon 30mg from Jul 10/13 and 10 x MS-IR 10mg from Jun 12/13 entries and again the audit shows zero inventory count and system count and shows they are expired.

Subsequently, at the March 2014 Inspection, Ms. Graves asked the Registrant when the last narcotic count and reconciliation was done. He advised that it had been done in response to the College's previous request which was in August 2013. Accordingly, approximately seven months had passed since the last narcotic count and reconciliation. Further, during the September 2014 inspection Ms. Jeon found a clear plastic bag containing more than 800 capsules of Methadone, a vial containing white powder labelled "Methadone" and a Ziploc bag labelled "Methadone 5 mg." with 5 mg. capsules inside and a stock bottle of Methadone Hydrochloride 100g. that had expired September 2012. These items had not been included in the August 2013 Narcotic and Controlled Drug Audit. The presence of these items, and the lack of information available in respect of these items such as when they were acquired by the Pharmacy (pre August 2013 or post August 2013), illustrates the consequence of a failure to maintain adequate narcotic count and inventory records. Without such information, there is

no way to determine what amount of Methadone should be within the pharmacy's inventory and whether any has gone missing. Ms. Jeon did request in a letter to the Registrant in January 2015 additional information about "documentation of narcotic request records for Methadone". The Registrant never responded to the request.

The evidence is clear that the Registrant has not complied with PPP-65.

(c)Cold Chain Management of Biologicals

PPP-68 (Cold Chain Management of Biologicals) sets out that the College adopts the BC Centre for Disease Control Guidelines on the Cold Chain Management of Biologicals. PPP-68 states that "cold chain" refers to the process used to maintain optimal temperature conditions during the transport, storage and handling of vaccines and other refrigerated pharmaceuticals. It recommends that the temperature for vaccine storage is at all times +2 degrees centigrade to +8 degrees centigrade and that vaccines are sensitive biological products and it is important to protect the vaccine potency and to maintain stability. Any loss of vaccine potency is permanent and irreversible. Exposure to excess light or heat or freezing may impact the potency and stability. It is important to know the correct storage conditions for each biological product and to ensure that each is kept under the recommended conditions.

The BC Centre for Disease Control, Management of Biologicals discusses appropriate cold chain equipment to store vaccines. Section 3.1 is entitled "Refrigerators". It specifically states that "standard "bar" fridges (small volume combination fridge/freezer with one exterior door) are not adequate because they do not maintain even temperatures". Items such as food and beverages should not be stored in vaccine refrigerators, so as to prevent unnecessary opening of the refrigerator. The refrigerator temperature should be between +2 degrees centigrade and +8 degrees centigrade. A temperature of +5 degrees centigrade provides an appropriate safety margin.

Mr. Lau, in his affidavit, indicated that he located a bar fridge which contained vaccines and insulin. The fridge was not incompliance with PPP-68 – it was bar fridge and the temperature (+12.6 degrees centigrade) was beyond the acceptable range. No temperature log was provided when Mr. Lau requested one from the Registrant.

The evidence is clear that the Registrant has not complied with PPP-68.

(d)Product Compounding Records

PPP-64 (Guidelines to Pharmacy Compounding) adopts the NAPRA Guidelines to Pharmacy Compounding as the Standard of Practice for Registrants. The NAPRA Guidelines state on page 5, under Recordkeeping, Section 7.2.3:

Information documented on each product should include, but not be limited to:

a. name, lot number and expiry of raw materials,

b. quantity required and quantity actually weighed,

c. the date of preparation and expiry,

d. initials/signature of compounder and/or pharmacist responsible for the preparation and checking,

e. written formula used,

f. records of stepwise operating/processing instructions and,

g. maintenance of training records.

Mr. Lau and Ms. Jeon seized 54 containers of drugs and NHPs from various locations in the Pharmacy during the March 2014 inspection including 52 products that were compounded. Compounding records for the 52 products should have been available for inspection. Mr. Lau and Ms. Jeon were only able to locate records for 30 products and, of the 30, 26 of the product records were missing some of the information required by the NAPRA Guidelines. Ms. Graves also advised in her memo regarding the March 2014 inspection, that she was unable to locate numerous prescriptions and compounding logs and that some of the compounding logs she located were missing information required under Section 7.2.3.

It is clear that PPP-64 was not complied with. The Registrant was, subsequent to the March 2014 inspection, asked to produce further compounding documentation. The Registrant did not respond to these requests.

(e)Failure to Properly Label Drugs and NHPs

The labelling requirements for compounded products and drugs are found in the NAPRA Guidelines and Schedule F of the HPA Bylaws, Section 9. Labels must include a list of active ingredients, the prescription or identification number of the compounded product and an estimated beyond use date printed at the end of the dosage duration. Ms. Jeon, Ms. Graves and Mr. Lau all observed, during their inspection in March and September, labels on a number of NHPs and products containing scheduled drugs found at the Pharmacy, which were missing some or all of the labelling requirements. The labelling requirements for compounded products and drugs in the NAPRA Guidelines and Schedule F of the HPA Bylaws Section 9 were not met.

(f)Sterile Equipment and Facilities

Section 12 of the NAPRA Guidelines sets out the requirements for sterile compounding as follows:

> 12.2 Carefully established standards for the operation of clean rooms and the preparation of sterile products should be documented in accordance with a recognized source (e.g. Canadian Society of Hospital Pharmacists).
>
> 12.3 Sterility testing shall be done according to a clearly defined standard (e.g. USP) and the product assigned an estimated expiry date.

Mr. Lau, was responsible for reviewing the room where sterile compounded appeared to be conducted (based on the fact that laminar flow hood (referred to as a Primary Engineering Control or PEC was located there). Mr. Lau, in his affidavit, indicated that PECs are typically used for the preparation of compounded products that require a sterile environment during compounding. The NAPRA Guidelines do not require application of a specific standard for the operation of clean rooms and preparation of sterile products nor do they mandate a specific standard for sterility testing. Mr. Lau, in his inspection, asked the Registrant if he was meeting the USP 797 Pharmaceutical Compounding – USP 797 Sterile Preparation. For example, USP 797 requires that a PEC and the buffer area around the PEC should be inspected every six months to ensure they meet applicability standards for sterile compounding. The Registrant advised Mr. Lau that the PEC had been in the Pharmacy for more than six months and that he had not scheduled any certification since its installation. Further USP 797 requires that the PEC provide an ISO Class 5 Environment. The Registrant was unable to produce any documentation that demonstrated that the PEC met ISO Class 5 standards.

USP 797 requires that the PEC Compounding Room meet ISO Class 7 standards. The Registrant was asked by Mr. Lau to produce any documentation in the form of a third party certification report showing that the PEC Compounding Room met ISO Class 7 standards. The Registrant did not provide any such documentation.

USP 797 also requires that the ante-area or ante-room (a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and also the area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling and other high particulate generating activities are performed) meet ISO Class 8 cleanliness standards. The Registrant informed Mr. Lau that he did not have an ISO Class 8 ante-area or ante-room.

The PharmaNet records indicate that in 2014, the Registrant was compounding drugs such as progesterone and testosterone which must be compounded using sterile compounding practices. Both of these drugs are identified and listed by The National Institute for Occupational Safety and Health (NIOSH) as hazardous drugs in healthcare settings. USP Chapter <795> states that hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel . In addition, items seized in

inspections such as a tetracycline eye ointment, needed to be prepared in a sterile environment to ensure patient safety.

Mr. Lau asked the Registrant to provide any other documentation other than USP 797 standard to demonstrate that proper sterility standards were being met. No such documentation was provided. The evidence is clear that the sterility requirements and standards were not being met.

(g)Inappropriate and Improper Prescribing Practices

PPP-58 (Medication Management – Adapting a Prescription) outlines when a pharmacist may dispense a drug contrary to the terms of a prescription. This is called adapting a prescription. A pharmacist may do so where it is intended to optimize the therapeutic outcome of the treatment with the prescribed drug. The policy outlines seven elements which must be met including:

> (i) obtaining the consent of the client or the client's representative, and
>
> (ii) notifying the original prescriber (and the general practitioner if appropriate) as soon as possible (preferably within 24 hours of dispensing) and this must be recorded in the client's record or directly on the prescription hard copy.

Further, certain drugs cannot be adapted pursuant to PPP-58. The Orientation Manual to PPP-58 excludes narcotics, controlled drugs and targeted substances. Also, according to the Orientation Manual, the pharmacist must indicate on the PharmaNet record that they have adapted the prescription by inputting their pharmacist identification number in the prescriber field of PharmaNet.

The PharmaNet records for 2013 and 2014 show numerous instances of the failure to comply with PPP-58. For example, the Registrant repeatedly adapted a prescription for a narcotic, or controlled drug contrary to PPP-58. This is most glaring in respect of adapted prescriptions of Teva-Nabilone and Cesamet with cannabis products. On a number of occasions, the Registrant adapted the prescription and dispensed cannabis related substances. This is adapting a prescription of a narcotic which is not permitted under PPP-58. Adapting a prescription for a narcotic or controlled drug was not limited to cannabis related products. This occurred also with testosterone (see Ms. Jeon's first affidavit paragraphs 126 and 127).

There were also numerous times when the prescribing physician either did not authorize the original prescription or its renewal. However, the Registrant did dispense a product but without a valid prescription. This occurred with respect Teva-Nabilone and Cesamet but it also occurred with titrated sertraline (Pollock affidavit, paragraphs 33-36), levodopa (first Jeon affidavit, paragraph 124-125), compounded desiccated thyroid (Graves affidavit, paragraph 16, first Jeon affidavit, paragraphs 132-135, second Tsui affidavit, Exhibit "A", page 34, first Jeon affidavit paragraphs 170 and 171),

compounded Eltroxin (Graves affidavit paragraph 16, first Jeon affidavit paragraphs 136-137), estrogen (Graves affidavit paragraph 16, first Jeon affidavit paragraphs 138-139), ketamine (Tsui supplementary affidavit paragraph 64, first Jeon affidavit paragraphs 148-149), Synthroid (second Tsui Affidavit, Exhibit A, page 46, first Jean affidavit paragraphs 172-173), compounded postnatal recovery PLC caps (Graves affidavit Exhibit "F1", page 48, page 61, first Jeon affidavit paragraphs 117-118, second affidavit Exhibit "A", page 22).

The evidence shows that PPP-58 was not complied with on numerous occasions.

As an example of unusual and conflicting PharmaNet information, the 2014 report shows that 500 Apo-naproxen DS 550 mg with DIN 1940309 was billed to PharmaNet with a day's supply of 15 with "Compounded suspension containing 175 mg naproxen per teaspoon, shake well" in the directions or sig field. The prescribing doctor confirmed that naproxen 175 mg suspension bid for 2 months with two repeats was ordered. Numerous questions arise:

1. Was 500 tabs or was 500 ml of a compounded suspension actually dispensed to the patient?
2. How is a day's supply of 15 determined with the 500 tablets when this is usually taken one tablet twice daily?
3. Why was the commercially available naproxen suspension not used?
4. Why do the drug and the directions not match?

Another example from the 2014 PharmaNet report indicates 100 Estraderm-25 patches billed with a day's supply of 15. The directions noted in the report are "Compounded Biest 1.25 mg (2:8) take one capsule a day lot RMB1901 Exp Jun".

As previously mentioned, the registrant did not attend the hearing and further clarification for these prescriptions was not obtained.

Allegations 10, 11, and 12

Manufacture, Storage and Dispensing of Drug Products Containing Cannabis Without a License
Receipt of Payments from Pharmacare for Drugs Not Actually Dispensed

Cannabis, its preparations, derivations and similar synthetic preparations are regulated under the Controlled Drug and Substances Act (CDSA). Under CDSA, the distribution and sale of substances listed in one of the schedules to CDSA is prohibited unless it is specifically authorized. Cannabis is listed in Schedule II of CDSA. As of 2013 and 2014, the principal exemption relating to the distribution and sale of cannabis products was found in the Marihuana for Medical Purposes Regulations (MMPR). This exemption related to "dried marihuana" only and required the person who was engaging in the distribution and sale to be a "licensed producer". There is also a limited exemption

for the sale of cannabis in the Narcotic Control Regulations which permit licensed dealers to sell or provide cannabis to a licensed producer.

Under the MMPR, three main activities are authorized:

(a) the possession of dried marihuana by individuals who have the support of an authorized health care practitioner;

(b) the production of marihuana by licensed producers, and

(c) the sale and distribution of dried marihuana by licensed producers and hospitals to individuals who can possess it.

Under the MMPR, a licensed producer was only able to conduct such activities, if they were licensed to do so and they conducted the activity in accordance with their license. Further, the MMPR did not allow dried marihuana to be sold or provide with any additive or in any dosage form, such as in a roll or capsule. The FDA and MMPR (through good production practices (GPPS)) established standards in respect of cleanliness of the premises and production equipment, training, quality assurance, and testing for microbial and chemical contaminants. The MMPR also established packaging and labelling requirements for dried marihuana.

Under the NCR, there is a limited right for pharmacists to sell dried marihuana provided that the pharmacist was practicing in a hospital and that the pharmacist was authorized to sell dried marihuana by the person in charge of the hospital. There is also a possible exemption under the CDSA for activities involving controlled substances including cannabis. This requires that the Minister of Health exempt a person from the provisions of the CDSA. Up to and including February 5, 2015 neither the Registrant, the Pharmacy nor the Corporation had been issued a license under the NCR or granted an exemption under the CDSA. Nor was the Registrant, Pharmacy or Corporation a licensed producer pursuant to the MMPR nor any application submitted by any of them to become a licensed producer. In effect, neither the Registrant, the Pharmacy or the Corporation were licensed to produce, sell or distribute cannabis or cannabis products.

During the September 2014 inspection, numerous cannabis products were seized indicating that manufacturing was taking place within the Pharmacy. These products were in many different dosage forms: capsules, lozenges, suppositories, patches, oils and edible pieces (see first Jeon affidavit). Ms. Jeon provided a photograph of a cannabis product prepared by the Pharmacy. The label read “Marigold Formula Compounded CBD 5:1 Ratio” and listed the Registrant as the prescriber or pharmacist. Similarly, with the product in dosage form of patches, lozenges and cookies.

The Registrant actually wrote to the College to explain the Pharmacy's method of preparing cannabinoids (Rees-Lee affidavit, paragraph 27). The PharmaNet records from January 1, 2013 to September 26, 2014, indicate that over 250 products were dispensed by the Registrant with the representation that they contained cannabis (Graves affidavit Exhibit "F1", Tsui Supplementary Affidavit, Exhibit "A"). In most cases, while the "drug use directions" in PharmaNet indicated that a compounded cannabinoid product was dispensed , the Registrant entered the dispensed drug as Cesamet or Teva-Nabilone which are synthetic commercially available cannabinoids and are a benefit drug under Pharmacare. Thus, although dispensing cannabis products, the Registrant was receiving payment from Pharmacare for a synthetic cannabinoid product. Cannabis products are not a benefit drug.

In addition, on three different occasions, cannabis products with the Pharmacy's label were returned to other pharmacies in the area. The three returned prescription bottles are each labelled differently: "compounded cbd 5:1", "compounded cannabinoid 5:1 ratio", and "compounded blended CBD (5:2.5 ratio)". PharmaNet records indicate that Teva-Nabilone 1.0mg was represented as being dispensed.

All of the cannabis products seized from the Pharmacy were sent to the RCMP. The RCMP sent the product to Health Canada for drug analysis. A report was received which indicated that of the products tested, all were positive for the presence of THC, the principle active ingredient in cannabis. Some of the products had not completed testing.

There is some evidence to indicate that as a result of the Registrant representing to PharmaNet that he was dispensing Teva-Nabilone or Cesamet, which are benefit drugs covered by PharmaNet, when he was actually dispensing cannabinoid products, that he was being overpaid by PharmaCare.

The College relies on a Final Desk Audit prepared by the PharmaCare Audit and Investigation Branch (Exhibit HH of the first Jeon affidavit"). The authors of the report did not appear as witnesses nor was there any affidavits provided by the authors. Nor has the College alleged any fraud on the part of the Registrant. The Ministry of Health has a number of remedies available to it if they believe that the Registrant and the Pharmacy have misled them and have received an overpayment including the authority to suspend Pharmacare payments payable to a pharmacy, the authority to impose administrative penalties, and the authority to terminate the Pharmacy Enrolment Agreement with the Pharmacy. The Panel was not advised as to whether the Ministry has taken any steps to enforce its remedies. Without additional evidence under oath from the Ministry, the Panel makes no finding on the allegation number 12 respecting any payments by PharmaCare to the Registrant or the Pharmacy. The evidence does clearly indicate that the Registrant sold and dispensed cannabis products without a license as required under CDSA or the NCA and that on occasion, the Registrant represented on PharmaNet that he was dispensing synthetic cannabinoid products when he was dispensing cannabinoid products.

This evidence is relevant to Allegations number 10 and 11 relating to manufacture, storage and dispensing of drug products containing cannabis. As indicated earlier, the Panel is treating the allegations contained in Allegations 10 and 11 as being illustrations of the alleged breaches in Allegations 1, 2 and 3 and are subsumed into those allegations. Thus, the evidence respecting the manufacture, storage and dispensing of cannabis products supports a finding that Allegations 1, 2 and 3 are proved, in particular in respect of the violations of CDSA and the MMPR.

Allegations 13, 14, 15, 16, 17, 18 and 19

Human Placenta Encapsulation
Manufacture and Dispensing of Drugs Containing Human Placenta Without a Valid Prescription

In 2013 and 2014, the Registrant dispensed 88 prescriptions for human placenta capsules (first Jeon affidavit, paragraph 112). The Registrant was indicated as the prescriber for approximately 64 of the prescriptions. The Registrant listed a registered midwife and a physician for some of the other prescriptions for human placenta capsules. When contacted by the College, both the registered midwife and the physician denied prescribing human placenta capsules for the named patients.

At the September 2014 inspection, Ms. Jeon and Ms. Rees-Lee found two bottles of placenta capsules in a fridge in the Compounding Room. The labels on the bottles said, “Marigold Formula Compounded Placenta Capsules”. There was no patient-specific information on the labels. This raises concerns about patient health safety. Compounding in a pharmacy practice is generally patient specific. In the case of human placenta this is very important. If placentas from different woman are pooled or if a placenta is used by an individual other than the mother, it raises the risk of transmission of infectious diseases.

The website of the Pharmacy had a section called “Placental Encapsulation” (see Pollock affidavit, Exhibit H). It outlines a number of “benefits” to placental encapsulation including:

> “It is rich in gonadotropin, the precursor to estrogen, progesterone and testosterone. This will prevent hair loss which is common after childbirth. It allows restoration of hormones to normal level, preventing mood swings and post-partum depression….
> It contains Oxytocin: for pain and bonding…
> The placenta restores the thyroid stimulating hormone which boosts energy and helps the mother’s recovery from stressful events...”

These statements, regardless of their accuracy or truthfulness, are a clear representation (or possible misrepresentation) as to the purported medicinal benefits for encapsulating human placenta.

As such they meet the definition of a "drug" under the FDA as that term is defined. A product that contains human placenta is a drug if it is manufactured, sold or represented for use in:

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals

(b) restoring, correcting or modifying organic functions in human beings or animals

Although it is unclear if the transformation of the human placenta of the mother into capsule form for her own use is the manufacture or sale of a placenta, it is clear that the representations contained on the website meet the definition of a drug for the purposes of the FDA. Further, the two bottles of placenta capsules found in the fridge with Marigold compounding labels without any specific patient identification information suggest that some of the human placenta capsules were being sold to women other than the original mother donor.

Human placenta capsules have not been approved by Health Canada for use in Canada under the FDA. It does not have a Drug Identification Number. As a consequence it is inappropriate for the Registrant to be compounding the product (as it is not an authorized drug for use in Canada, see POL-0051; see also NAPRA Guidelines) or to be dispensing it until a standard has been developed for it.

The evidence is clear that the Registrant dispensed drugs containing human placenta to patients without a valid prescription, sometimes using the name of a health practitioner improperly, when Health Canada had not approved human placenta as a drug. Allegations 14 through 19 are proved. Again, as with Allegations 10 and 11, the Panel views Allegations 14 to 19 relating to human placenta manufacture and dispensing as being subsumed into Allegations 1, 2 and 3. The evidence in respect of human placenta manufacture and dispensing support the finding that breaches of the FDA have occurred. Further, the use of other health care providers as prescribers without their knowledge or consent violates not only the policies of the College but also generally accepted standards of pharmacy practice.

Allegation 13, which alleges that the Marigold website misrepresented the efficacy of human placenta as a drug, was not proved as no evidence was led as to the efficacy of the registrant's representations.

Allegation 20

Failure to Co-operate with College Investigation

The College alleges that the Registrant failed to co-operate with the College in its investigation. The College alleges two distinct failures.

The first is the misrepresentation about the ability of the Registrant and Pharmacy to manufacture drugs and NHPs without a license. According to Ms. Jeon in her first affidavit, at

paragraph 30, the Registrant informed Ms. Jeon that, although he had not obtained either an establishment license or a site license, he was in the process of obtaining those licenses and that there was a grace period allowed by Health Canada during which he could manufacture drugs and NHPs without the necessary license. Health Canada subsequently informed Ms. Jeon that there is no such grace period.

The College, in their submission to the Panel, characterized the Registrant's comment to Ms. Jeon as "the Registrant advised that he and the Pharmacy had received permission from Health Canada to manufacture drugs and NHPs on an interim basis, while the applications for the requisite licenses were pending". A review of Ms. Jeon's affidavit at paragraph 30 does not indicate that the Registrant said that Health Canada had given him permission to manufacture drugs and NHP but rather that the Registrant believed there was this grace period. The basis for this belief, for example, Health Canada advised him or he had read it somewhere or had been told that by somebody not associated with Health Canada, was not explored with the Registrant by Ms. Jeon.

It is possible that the Registrant believed that a grace period existed. Further, the Registrant advised that he "was in the process of obtaining those licenses". Ms. Seeling in her affidavit advises that no Establishment License or Site License had been issued to the Registrant or Pharmacy up to and including December 11, 2014. Ms. Seeling does not state that no application had been received by Health Canada for a site license or establishment license.

Given that Health Canada has not indicated that the Registrant and Pharmacy have not applied for a license and that the Registrant did not say to Ms. Jeon that Health Canada had advised him of the "alleged" grace period it's not possible to say that the Registrant deliberately misled the College on the question of a grace period. He may have been mistaken.

The second alleged failure to co-operate is the Registrant's failure to respond to a series of emails/letters from the College seeking further information from the Registrant. Ms. Jeon, in her first affidavit, sets out a series of emails and letters sent to the Registrant beginning in March 2014 (first Jeon affidavit, Exhibits "WWWW", "YYYY", "ZZZZ, "AAAAA", "BBBBB", "CCCCC, and "DDDDD"). The first three emails/letters (Exhibit "WWWW", "YYYY", "AAAAA") express appreciation for the Registrant's continued cooperation. The last three emails/letters do not express appreciation for co-operation but neither do they warn the Registrant that failure to co-operate may result in charges against the Registrant. Further, in the Inquiry Committee's Complaint Disposition Report from January 30, 2015 meeting, it states at page 61 of the Report, in reference to the failure of the Registrant to respond to enquiries. "The Registrant is not obligated to respond". If failure to respond is intended to be the basis of an allegation of failure to co-operate, then this should be clearly brought to the attention of the Registrant by the College in their communication with the Registrant.

Accordingly, the evidence presented by the College does not support a finding that the Registrant failed to co-operate with the College's investigation. Allegation 20 is not proved.

Allegation 21

Misrepresentation of Educational Qualifications

The website of the Pharmacy contains the following statement respecting the Registrant: "he trained as a Manufacturing and Formulating Chemist at the University of British Columbia as part of the Manufacturing Pharmacy Residency Program" (Exhibit "FFFFF" first Jeon affidavit).The College asserts that this statement is untrue and that no such educational program existed. Ms. Jeon contacted the Faculty of Pharmaceutical Sciences at the University of British Columbia to enquire if the Faculty has ever had a residency program called the "Manufacturing Pharmacy Residency Program". Dr. Michael Coughtrie, Dean of the Faculty of Pharmaceutical Sciences, responded to Ms. Jeon (Exhibit "GGGGG") advising that the Faculty does not have a residency program entitled "Manufacturing Pharmacy Residency Program" nor has it ever had such a program in the past. However, he advised that the Registrant did take a two-credit course in Manufacturing Pharmacy in 1978-79. He further stated that this course was not a Residency Program.

Section 83 of the HPA Bylaws states that:

83(5) Any marketing undertaken or authorized by a registrant in respect of his or her professional services must not be:

(a) false

(b) inaccurate

(c) reasonably expected to mislead the public, or

(d) unverifiable

83(6) Marketing violates subsection (5) if it:

(b) is likely to create in the mind of the recipient or intended recipient an unjustified expectation about the results which the registrant can achieve.

The statement that the Registrant trained as a Manufacturing and Formulating Chemist at the University of British Columbia as part of the Manufacturing Pharmacy Residency Program is incorrect as there is no such Residency Program. However, he did take a Manufacturing Pharmacy course. What is the effect of the reference to a Residency program which doesn't exist? Does it convey to someone reading the statement that the Registrant has a particular expertise, over and above a regular pharmacist? The College in effect says that the words speak for themselves. No evidence was presented to show the effect of the additional words nor what is meant or understood by the phrase "Manufacturing Pharmacy Residency Program".

The statement on the website is inaccurate and as such is a breach of Section 83(5)(b) of the HPA Bylaw. The effect and impact of such a breach is less clear. The evidence supports a finding that the statement on the website was untrue as alleged in Allegation 21.

Summary of Evidence and Analysis

The College bears the onus of proof in this matter. The Panel has carefully considered all the evidence provided and the submissions of counsel. In reaching our conclusions, the Panel has applied the civil standard of proof on a balance of probabilities as per F(H) v. McDougall 2008 SCC 53 (CanLii). In McDougall, the Supreme Court of Canada stated that evidence must always be sufficiently clear, convincing and cogent to satisfy the balance of probabilities test (para. 46).

The Panel finds that the evidence presented by the College establishes that the Registrant both as Manager, Director and Owner of Marigold Pharmacy and as the only pharmacist practicing pharmacy at the premises acted in contravention of the HPA and bylaws there to, PODSA and bylaws there to, the CDSA and regulations there to including both the MMPR and the NCR, the FDA and regulations there to including FDR and NHPR, the College's PPP, the NAPRA Guidelines, POL-0051 and generally accepted standards of pharmacy practice. The storage and sale of cannabis products and the production and dispensing of human placenta capsules are examples of not only the violation of the CDSA and FDA but also of the improper use of adaptation by the Registrant. The overwhelming evidence of manufacturing without obtaining the requisite establishment licenses and site licenses under the Food and Drug Regulation and the Natural Health Product Regulation as well as the failure to provide sterile compounding/manufacturing facilities illustrate both breaches of standards and regulation and also the failure to comply with PPPs. The concerns about labelling, expiry dates, and the lack of proper refrigeration equipment are further examples of the failure to observe the professional standards expected and required of a licensed pharmacist. The Registrant was the owner and operator of the Pharmacy. He was the manager responsible for supervising and overseeing the operations and staff of the Pharmacy He was the only pharmacist on record for the Pharmacy and as such is responsible to ensure the acts, regulations, bylaws, policies and standards relevant to the practice of pharmacy were observed at the Marigold's premises.

The Panel finds Allegations 1, 2, and 3 are proved.

The evidence is also clear that the Registrant as Registrant and as Manager, Owner and Director of the Pharmacy failed to comply with the terms of the Consent Agreement dated September 14, 2011 between the Registrant, as Registrant and Manager, and as Director and Owner of Marigold and the Inquiry Committee of the College. As far back as 2010, concerns were raised about the operations of the Pharmacy and in particular, issues relating to manufacture and compounding of drugs and natural health products and the failure to obtain the requisite Establishment and Site Licenses.

Concerns were also raised about compliance with NAPRA guidelines and Health Canada's POL-0051. All of these concerns were raised again in the March 2014 and the September 2014 inspections after the Registrant had undertaken to comply with the relevant act, regulations and policies. Concerns were also raised in 2010 about the need for valid prescriptions and compliance with PPP-58, concerns which subsequently arose again in March and September 2014. The Panel finds that Allegation 4 is proved.

Allegation 5 (lack of Establishment License), Allegation 6 (lack of site license), Allegation 7 (improper manufacture of drugs and NHPs), Allegation 8 (improper compounding of drugs and NHPs) are all subsumed by and are specific illustrations of the breaches of acts, regulations, bylaws, policies and standards referred to in Allegations 1, 2, and 3. Accordingly, the Panel makes no separate finding on Allegations 5, 6, 7 and 8. They are part of and examples of the various wrongs alleged in Allegations 1, 2, and 3.

Allegation 9 involves the Registrant's signing of an Inspection Reply Form in which the Registrant advised of compliance with PPPs. Inspector Graves detailed the deficiencies identified which were to be corrected in her affidavit, paragraphs 6 and 7. The Registrant signed an Inspection Reply Form on August 9, 2013 advising that the deficiencies had been corrected. The deficiencies related in part to improper refrigeration equipment, narcotic count and reconciliation, separating narcotic prescriptions from non-narcotic prescriptions, removal of expired products from shelves, improper labelling, and questions about sterilization equipment and facilities. All again were concerns and issues identified in the March 2014 and September 2014 inspections. The failures were not properly addressed and the Registrant misled the College in his signing of the Inspection Reply Form indicating that the deficiencies had been corrected. Allegation 9 is proved.

Allegation 10 and 11 relating to the manufacture, storage and dispensing of drug products containing cannabis contrary to the MMPR are dealt with in Allegations 1 and 2. No separate finding on Allegation 10 or 11 is required.

Allegation 12 relates to improper billing by the Registrant of PharmaCare and primarily the dispensing of cannabis drug products when synthetic cannabis products (Cesamet or Nabilone) were entered as the dispensed drug in PharmaNet. The evidence relied upon by the College is a PharmaCare Audited Investigation Report Investigation report which was introduced as an exhibit in first Jeon affidavit (Exhibit HH). It is unsworn evidence. Ms. Jeon cannot testify as to the accuracy of the report. The allegation is a serious allegation in the nature of fraud and accordingly one would expect that the evidence respecting it would be given under oath by the person or persons who conducted the audit. The Audit report's conclusions are based upon the fact that the Pharmacy failed to provide sufficient invoices to support the ingredient costs associated with the volume of the alleged dispensed items. The audit does not allege that the Respondent supplied cannabis products to patients improperly but rather that the pharmacy failed to provide sufficient documentation to support the quantity of drugs billed to PharmaCare. The Audit's conclusion was that the Pharmacy was overpaid $[redacted] for insufficient

invoices to support ingredient costs. To the extent that Allegation 12 refers to the inappropriate dispensing of cannabis products by adapting or altering prescriptions of Cesamet or Nabilone, these actions form part of the basis for Allegations 1, 2, and 3 and are dealt with in that context. Allegation 12 is not proved.

Allegation 13 alleges that the Registrant made unsupported claims on the Marigold website regarding the efficacy of human placenta as a drug thereby misleading the public. The College introduced no evidence as to the efficacy of human placenta as a drug. Allegation 13 is not proved.

Allegations 14 to 19 (inclusive) related to the encapsulation of human placenta and dispensing of human placenta capsules including the inappropriate use of other health care practitioners as prescribers. These topics are covered by the allegations contained in 1, 2, and 3.

Allegation 20 relates to the failure of the Registrant to co-operate with the investigation by providing false information and failing to respond to letters/emails. On the first point, the Registrant responded to the Inspector's question with an answer that was incorrect. However, it is not clear that the Registrant believed that his answer was incorrect. The evidence of Ms. Jeon characterized the answer as being based on a particular set of facts (the information was received from Health Canada) whereas Ms. Jeon never stated in her evidence the basis or source of the Registrant's belief. An incorrect answer is not necessarily a failure to co-operate. The other instances of failure to co-operate relate to a series of unanswered letters. The initial letters thank the Registrant for his co-operation. The later letters are quiet on the issue of co-operation and specifically, make no mention of the possibility of the consequences of failure to respond, namely the possibility of being cited for failure to co-operate. If the college intends to rely on a failure to respond as a basis of non co-operation, one would expect both a warning to that effect and proof that the Registrant had received the letters/emails. Allegation 20 is not proved.

Lastly, Allegation 21 relates to the statement about the Registrant's training at the University of British Columbia, specifically a reference to "Manufacturing Pharmacy Residency Program". No such residency program existed at UBC. However, the Registrant did take a two-credit course entitled "Manufacturing Pharmacy". Allegation 21 is proved.

Penalty

The Panel finds that Allegations 1, 2, 3, 4, 9 and 21 are proved. Allegations 5, 6, 7, 8, 10, 11, 14, 15, 16, 17, 18 and 19 are, based on the evidence presented and the broad nature of the breaches contained in the first three allegations, subsumed into and form part of the first three Allegations. Allegations 12, 13, and 20 are not proved.

The effect of the finding that the said allegations are proved means that the Registrant has engaged in unprofessional conduct (as per Section 39(1)(c) of the HPA) and failed to comply with the

HPA, its regulations and bylaws (as per Section 39(1)(a) of the HPA). Unprofessional conduct captures conduct, done in the pursuit of one's profession, which would be reasonably regarded as improper by his professional peers, of good repute and competency. There can be no doubt the conduct of the Registrant would shock his professional peers and be condemned by them.

The College has also raised the issue of whether the Registrant's conduct also amounts to incompetence. In Mason v Registered Nurses Association of BC (1979 CanLII 419 BCSC), the Court defined incompetence as the want of ability suitable to the task. This may arise not only from a lack of experience or skill but also from a deficiency of disposition to use one's abilities or experience properly. Further, the Court stated that conduct which demonstrates a pattern of carelessness and the person is of a disposition or temperament whereby they fail to respond to advice as to their shortcomings, could be considered incompetence.

In this case, the Registrant has had his deficiencies in his conduct pointed out to him a number of times. He has been advised of the requirements respecting the manufacture and compounding of drug products and natural health products as far back as 2010. He is aware of the necessity to maintain appropriate sterile equipment and facilities and indicated an intention to stop the manufacture/compounding of products due to the absence of a sterile facility. He is aware of the need to obtain the appropriate licenses and permits. He has also been advised and is aware of the requirements for the proper labelling of products. And yet these deficiencies continue to occur including the continued manufacture/compounding of products in a non-sterile environment. A pattern of carelessness and continued deliberate failure to correct these deficiencies support a finding of incompetence in respect of Allegations 1, 2, and 3.

Further, the College has raised the issue of ungovernability. The College has pointed to the Registrant's unwillingness to participate in the College's investigation and the hearing itself as a basis for ungovernability. However, the Panel finds that the evidence of the Registrant's continued failure to comply with the rules and standards of the profession even after these have been brought to his attention, both in the Consent Agreement and the Inspection Reply Form, support a finding of ungovernability. Further, the Registrant has, through his conduct, deliberately misled and misinformed the College as to his actions and the corrective measures he has undertaken. He has indicated an intention to meet the statutory regime and professional standards expected of a registrant of the College. He signs a Consent Agreement to abide by the relevant statutes, regulations, and policies. He signs an Inspection Reply Form advising that the identified deficiencies have been addressed. He advises the College that he will not engage in the manufacture or compounding of sterile products because of the lack of the appropriate needed facilities and the cost to meet the standards required. And yet, the Registrant continues with his conduct. As stated in the Law Society of Manitoba v Ward [1996] LSDD No 119, "the justification for self-government is at least partly based on the assumption that the

Society will in fact govern its members and that members will accept governance". The Registrant has through his conduct demonstrated that he does not accept that governance.

The College is only seeking a penalty against the Registrant. The Pharmacy's pharmacy license was suspended as of September 26, 2014 and the suspension has not been lifted nor the license renewed. The Pharmacy is closed. The Corporation's role and duty as owner of the Pharmacy only continued during the currency of the Pharmacy's license. The College is not seeking any action against the Pharmacy or the Corporation accordingly.

The College asserts that the conduct of the Registrant presented a clear and direct risk of harm to the public. He manufactured drugs and natural health products without the requisite license in a facility that lacked appropriate sterility equipment and facilities. He failed to maintain proper records in respect of prescriptions, compounding and products. He had inappropriate products in the Professional Product Area. He did not maintain proper cold chain management of vaccines and insulin. Drugs were dispersed inappropriately without proper adaptation of prescriptions and under the wrong drug name. He improperly provided cannabis products and human placenta capsules to clients

The Registrant has not attended the hearings and has not provided any evidence to suggest contrition or remorse for his conduct or even any explanation for his behaviour. He has faced disciplinary action for similar conduct in 2010 and signed a Consent Agreement after having been suspended and the Pharmacy's license suspended.

The College is seeking a cancellation of the registration of the Registrant. The Panel is in agreement that a cancellation is appropriate both as a matter of specific deterrence of the Registrant but also as a reflection of the need to maintain the public's confidence in the College's commitment to public safety and the regulation of its members. In the Panel's view, cancellation with strict conditions for the reinstatement is appropriate. Practice conditions will be set forth by the "Registration Committee" at the time of reinstatement.

The College is also seeking to recover its costs in connection with the preparation for and resolution of the discipline hearing. The HPA provides that a discipline panel may award costs to the College against a respondent based upon a tariff of costs, such costs not to exceed 50% of the actual costs to the College for legal representation for the purposes of the hearing (Sections 39(5) and 39(7) of the HPA). Schedule E of the College's Bylaws entitled Tariff of Costs, states in paragraph 3 and 4 that the College may recover expenses for legal representation for the purposes of preparing for and conducting the hearing to the maximum of 50% of actual legal fees incurred.

The Panel has been provided with the 4th affidavit of Ms. Valerie Tsui. Ms. Tsui states, in her affidavit, that the College is asking the Panel to award costs in the amount of $115,000.00. This amount, she states, has been calculated based on Paragraphs 3 and 4 of the Tariff of Costs, Schedule E of the College's Bylaws and does not exceed, in total, 50% of the actual cost to the College for its own legal representation for the purpose of the hearing.

The hearing occurred over a period of three weeks with eight days of hearing. The College provided extensive affidavit evidence (nine different persons provided affidavits and some individuals provided multiple affidavit). There were a large number of allegations with extensive particulars. The allegations raised serious issues about the conduct of the Registrant. The Panel was satisfied that the Registrant's conduct was unprofessional conduct and in some instances also amounted to incompetence.

The Registrant's failure to engage with the College both in respect of the substance of the allegations and, more directly, in respect of the procedure of the discipline process (service of documents, notice of proceedings, attendance at hearings) contributed to the length of the hearing process and the degree of detail that the College determined to be necessary to fully prove their case. As such, it is appropriate that the Registrant bear some responsibility for the high costs of the proceedings.

Considering all of the above, the Panel is of the view that the College is entitled to recover the full amount of costs as provided for in the Tariff of Costs, specifically 50% of the actual legal fees incurred for its own legal representation for the purposes of the hearing. The Panel awards costs of $115,000.00.

Order

The Panel:

(a) orders:

(i) cancellation of the registration of the Registrant, and

(ii) costs of $115,000 based upon the tariff in Schedule E of the College's Bylaws

(b) orders that, subject to subparagraph (c), the Registrant will only be eligible to apply for reinstatement of registration six years following the date of the Panel's order.

(c) orders that the Registrant must have paid in full the costs ordered to be paid by the Panel in order for the Registrant to be eligible to apply for reinstatement of registration.

(d) orders that for a period of five years following any reinstatement of registration, the Registrant will not be eligible to:

(i) apply for a pharmacy license, or

(ii) act as a pharmacy manager or pharmacy director.

The respondents have the right to appeal this order to the Supreme Court of British Columbia as provided in section 40 of the *Health Professions Act*, [RSBC 1996] chapter 83, a copy of which is appended to this decision.

By the Discipline Committee:

[redacted]

Wayne Chen, Chair — May 31, 2018 (Date)

[redacted]

Jody Croft — June 1, 2018 (Date)

[redacted]

Howard Kushner — May 29, 2018 (Date)

Appeal of discipline committee decision to Supreme Court

40 (1) A college, a respondent described in section 38 (2) or a registrant described in section 39.1 (1), aggrieved or adversely affected by an order of the discipline committee under section 39 or 39.1 (1), may appeal the order to the Supreme Court.

(2) An appeal under this section must be commenced within 30 days after the date on which the order described in subsection (1), or the written notice described in section 20 (7), as the case may be, is delivered to the person who has the right to appeal under this section.

(3) An appeal under this section must be commenced by filing a petition in any registry of the Supreme Court, and the Supreme Court Civil Rules relating to petition proceedings apply to the appeal, but Rule 18-3 of those rules does not apply.

(4) The petition commencing an appeal under this section must, within 14 days of its filing in the court registry, be served on

(a) the college, effected by service on the registrar, if the appellant is a respondent described in section 38 (2) or a registrant described in section 39.1 (1),

(b) the respondent or the registrant, if the appellant is the college, and

(c) the complainant, if the matter relates to a complaint.

(5) Only the persons required to be served under subsection (4) (a) and (b) may be parties to an appeal.

(6) [Repealed 2008-29-42.]

(7) On request by a party to an appeal under subsection (1) and on payment by the party of any disbursements and expenses in connection with the request, the registrar must provide that party with copies of part or all, as requested, of the record of the proceeding before the discipline committee.

(8) An appeal under subsection (1) must be a review on the record unless the court is satisfied that a new hearing or the admission of further evidence is necessary in the interests of justice.

(9) On the hearing of an appeal under this section, the court may

(a) confirm, vary or reverse the decision of the discipline committee,

(b) refer the matter back to the discipline committee, with or without directions, or

(c) make any other order it considers appropriate in the circumstances.

(10) A decision of the Supreme Court on an appeal under subsection (1) may be appealed to the Court of Appeal if leave to appeal is granted by a justice of the Court of Appeal.

THE MATTER OF THE COLLEGE OF PHARMACISTS OF BRITISH COLUMBIA

AND

ISIDORO ANDRES "RUDY" SANCHEZ, MARIGOLD COMPOUNDING and NATURAL PHARMACY and MARIGOLD NATURAL PHARMACY LTD.

CORRIGENDUM TO DECISION ON HEARING OF CITATION BY THE COLLGE OF PHARMACISTS

(Wayne Chen, Chair, Jody Croft, Howard Kushner)

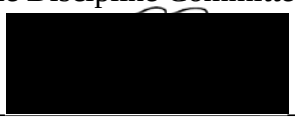
Hearing Date:	October 16-18, November 6-8, November 14-15, 2017 Vancouver, B.C.
Date of Corrigendum:	August 22, 2018
Counsel for the College of Pharmacists of B.C.	Mr. D. Lebans, and Ms. R. Egit
Counsel for Isidoro Sanchez and Marigold Compounding and Natural Pharmacy	Self-represented, did not attend the hearing
Counsel for the Discipline Panel:	Ms. M. Baird, Q.C.

This is a corrigendum to the reasons of the hearing panel issued on or about June 1, 2018. Reasons for the corrigendum are issued separately.

The following sentence is added to the Order of the hearing panel, after (d) of the order:

"The respondents have the right to appeal this order to the Supreme Court of British Columbia as provided in section 40 of the *Health Professions Act*, [RSBC 1996] chapter 83, a copy of which is appended to this decision."

By the Discipline Committee:



Wayne Chen, Chair — August 22, 2018 — Date

Jody Croft — August 22, 2018 — Date

Howard Kushner — August 22, 2018 — Date

THE MATTER OF THE COLLEGE OF PHARMACISTS OF BRITISH COLUMBIA

AND

ISIDORO ANDRES "RUDY" SANCHEZ, MARIGOLD COMPOUNDING and NATURAL PHARMACY and MARIGOLD NATURAL PHARMACY LTD.

REASONS FOR DECISION ON RE-ISSUANCE OF ORDER AND CORRECTION OF ORDER

(Wayne Chen, Chair, Jody Croft, Howard Kushner)

Hearing Date:	October 16-18, November 6-8, November 14-15, 2017 Vancouver, B.C.
Date of Submission on Re-Issuance of Order and Correction of Order:	Written submission dated July 25, 2018
Date of Decision on Re-Issuance of Order and Correction of Order:	August 22, 2018
Counsel for the College of Pharmacists of B.C.	Mr. D. Lebans, and Ms. R. Egit
Counsel for Isidoro Sanchez and Marigold Compounding and Natural Pharmacy	Self-represented, did not attend the hearing
Counsel for the Discipline Panel:	Ms. M. Baird, Q.C.

[1] The hearing panel delivered its written reasons for decision, including its order, on or about June 1, 2018.

[2] On July 10, 2018, counsel for the College wrote to counsel for the hearing panel. In that email, College counsel drew to the attention of the hearing panel that its order did not include a statement advising the respondents of their appeal rights under the *Health Professions Act* (the "Act") as required by section 39(1)(3)(d) of the Act. College counsel also advised that the College had not delivered the written reasons of the hearing panel to the respondents within the 30 day time period specified in section 39(1)(3)(c) of the Act, and that no public notice of the decision had been made.

[3] College counsel suggested that it would be appropriate for the hearing panel to add the section 39(1)(3)(d) reference to appeal rights to its order and to re-issue the decision which would be dated as of the date of the addition of the appeal rights.

[4] By email dated July 18, 2018, the hearing panel asked for a written submission on the jurisdiction to revise its reasons for decision to include in the order a reference to the respondents' right to appeal. The hearing panel also asked the College to address the form in which this should be done, adding:

> "It is the panel's present view that this should be done by way of issuance of a corrigendum or an amended decision which would be dated as of the date any decision to amend the decision/order to add the appeal provision was made, however it wishes to have the College address this issue in its submission."

[5] The written submissions of the College were received on July 25, 2018. The hearing panel has considered the College's submission and has decided as follows.

[6] The inadvertent omission of the respondent's statutory appeal rights in its order is a technical defect, which in no way alters the substance of the decision of the hearing panel. Further, the obligation to advise of the appeal right is a procedural requirement that arises because the hearing panel is issuing an order under section 39(3) of the Act. As such, it falls within the authority of the common law allowing tribunals to amend decisions as articulated in the literature and cases. (*Practice and Procedure before Administrative Tribunals* (Macauley, Robert W. and Sprague, James L.H. Scarborough: Carswell, 2001) at p. 27A-6; *Colbert v. District of North Vancouver (No.2),*2018 BCHRT 46, paras 4-6.).

[7] Further, the authority to amend decisions is consistent with a statutory tribunal's implied power to act in a manner that is reasonably necessary to accomplish its mandate (*ATCO Gas and Pipelines Ltd. v. Alberta (Energy and Utilities Board),* 2006 1 S.C.R. 140 at para 51; *Joshi v. British Columbia Veterinary Medical Association,* 2010 BCCA 129).

[8] The hearing panel does not accept that the amendment to its decision to add the statutory appeal rights can be done by the re-issuance of its order in amended form bearing the date of this decision. It is the panel's view that this would, in effect, be a re-creation of an historical fact, the date when the order being amended was, in fact, issued. The panel also believes that the suggested re-issuance would not meet the important criteria of transparency. Therefore, while the panel is satisfied that it has the authority to amend the order to add the statutory rights, it believes that the

appropriate way to do this is by corrigendum. (*Grant v. City of Vancouver and others* (No. 4), 2007 BCHRT 206 (CanLII)).

[9] Accordingly the panel's order is amended to add the following:

> "The respondents have the right to appeal this order to the Supreme Court of British Columbia as provided in section 40 of the *Health Professions Act*, [RSBC 1996] chapter 83, a copy of which is appended to this decision."
>
> This sentence will be added after (d) in the order.

By the Discipline Committee:

[redacted]

Wayne Chen, Chair — August 22, 2018 Date

[redacted]

Jody Croft — August 22, 2018 Date

[redacted]

Howard Kushner — August 22, 2018 Date