College of Pharmacists
of British Columbia

THE COLLEGE OF PHARMACISTS OF BRITISH COLUMBIA

and

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

CITATION

To: Isidoro Andres "Rudy" Sanchez, Marigold Compounding and Natural Pharmacy and Marigold Natural Pharmacy Ltd.
[redacted]

And to: Isidoro Andres "Rudy" Sanchez, Marigold Compounding and Natural Pharmacy and Marigold Natural Pharmacy Ltd.
[redacted]

A. TAKE NOTICE THAT the Discipline Committee of the College of Pharmacists of British Columbia (the "College") will inquire into your conduct as a Registrant, as Manager of Marigold Compounding and Natural Pharmacy and as Director and Owner of Marigold Natural Pharmacy Ltd., pursuant to Parts 2.2 and 3 of the *Health Professions Act* RSBC 1996 c.183 (the "*HPA*") and sections 1, 5(3), 7, 9, 10, and 29 of the *Pharmacy Operations and Drug Scheduling Act* SBC 2003 c.77 *("PODSA").*

B. In this Citation, Marigold Compounding and Natural Pharmacy and Marigold Natural Pharmacy Ltd. shall collectively be referred to as "Marigold". At all material times Marigold is alleged to have operated from premises at 100-576 England Avenue, Courtenay, B.C. V9N 2N3, which shall be referred to herein as the "Premises".

C. The proceedings will commence at **9:30am on January 19, 2017** at the College at suite **200 - 1765 West 8th Avenue, Vancouver, B.C. V6J 5C6** for a case management conference to set dates for the taking of evidence and to consider such matters as the Registrant, counsel or the Discipline Committee may advise.

D. The Discipline Committee will consider whether as Registrant, Manager, Director and Owner you have committed offences pursuant to sections 25.91 to 25.93 inclusive and 39(1)(a) – (d) inclusive of the *HPA* and sections 20, 29(2) and 29(3) of *PODSA* as follows:

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1. Between March 1, 2013 and September 30, 2014 in breach of your duties as Manager, Director and Owner of Marigold you permitted, encouraged and directed the conduct and management of the practice of pharmacy at the Premises in contravention of the *HPA* and bylaws thereto; *PODSA* and bylaws thereto; the *Controlled Drugs and Substances Act,* SC 1996, c19 (*"CDSA")* and regulations thereto including the *Marihuana for Medical Purposes Regulations* SOR/2003-119 (*"MMPR")* and the *Narcotic Control Regulations,* CRC, c 1041 ("*NCR")*; the *Food and Drugs Act* [RSC 1985] c F-27 ("*FDA")* and regulations thereto including the *Food and Drug Regulations* CRC, c 870 *("FDR")* and *Natural Health Products Regulations* SOR/2003-196 (*"NHPR");* the College's Professional Practice Policies ("PPPs"); the *Guidelines to Pharmacy Compounding 2006* published by the National Association of Pharmacy Regulatory Authorities ("NAPRA Guidelines")*;* the *Policy on Manufacturing and Compounding Drug Products in Canada* published by Health Canada ("POL-0051"); and generally accepted standards of pharmacy practice;

2. Between March 1, 2013 and September 30, 2014 as Registrant and Manager you practiced pharmacy at the Premises in contravention of the *HPA, PODSA*, the bylaws thereto, the PPP's and generally accepted standards of pharmacy practice;

3. Between March 1, 2013 and September 30, 2014 as Registrant, Manager, Director and Owner, you failed to supervise the practice of pharmacy at the Premises by Registrants, Support Persons and other staff, thereby permitting the practice of the profession of pharmacy in contravention of the *HPA* and bylaws thereto; *PODSA* and bylaws thereto; the *CDSA* and regulations thereto including the *MMPR* and the *NCR*; the *FDA* and regulations thereto including the *FDR* and the *NHPR*; the PPP's; the NAPRA Guidelines; POL-0051; and generally accepted standards of pharmacy practice;

4. Between January 1, 2013 and September 30, 2014 as Registrant and Manager, Owner and Director, you failed to comply with the terms of a consent agreement dated September 14, 2011 between yourself as Registrant and Manager, and as Director and Owner of Marigold and the Inquiry Committee of the College;

5. Between April 1, 2013 and September 30, 2014 as Registrant, Manager, Director and Owner, you, Support Persons and Marigold staff manufactured drugs at the Premises without having obtained a Drug Establishment Licence contrary to section C.01A.004 of the *FDR*;

6. Between April 1, 2013 and September 30, 2014 as Registrant, Manager, Director and Owner, you, Support Persons and Marigold staff manufactured natural health products ("NHPs") without having obtained a Site Licence contrary to section 27(1)(a) of the *NHPR*;

7. Between March 1, 2014 and September 30, 2014 as Registrant, Manager, Director and Owner, you, Support Persons and staff at Marigold manufactured drugs and NHP*s* at the Premises in a manner contrary to generally accepted standards of manufacturing, the *NHPR* and the *FDR*;

8. In the alternative, between March 1, 2014 and September 30, 2014 as Registrant, Manager, Director and Owner, you, Support Persons and staff at Marigold compounded drugs and NHP*s* contrary to PPP 64, the NAPRA Guidelines, POL-0051, and generally accepted standards of pharmacy compounding;

9. On or about August 9, 2013 by means of an Inspection Reply Form you advised the College that as a Registrant, Manager, Owner and Director of Marigold you had corrected deficiencies in pharmacy practice at the Premises by yourself, Support Persons and Marigold staff, including compounding practices identified by College inspectors on July 9, 2013 when this was untrue;

10. Between October 1, 2013 and September 30, 2014 as Registrant, Manager, Director and Owner you engaged in the manufacture, storage and dispensing of drug products containing cannabis, contrary to the *MMPR* and *NCR*;

11. In the alternative, between October 1, 2013 and September 30, 2014 as Registrant, Manager, Director and Owner you permitted and authorized Support Persons and Marigold staff to engage in the manufacture, storage and dispensing of drug products containing cannabis, contrary to the *MMPR* and *NCR* ;

12. Between October 1, 2013 and September 30, 2014 as Registrant, Manager, Director and Owner, you, Support Persons and staff at Marigold submitted billings to PharmaCare and received payment from PharmaCare in the amount of $25,542.06 for the drugs Cesamet or Nabilone, which are commercially available drugs containing cannabis approved by Health Canada, when an unapproved drug product containing cannabis manufactured by you, Support Persons and/or Marigold staff had been dispensed;

13. On August 29, 2014 as a Registrant, Manager, Owner and Director you made unsupported claims on the Marigold website regarding the efficacy of human placenta as a drug thereby misleading the public;

14. Between March 1, 2013 and September, 30 2014 on 85 occasions as Registrant, Manager, Owner and Director you manufactured and dispensed drugs containing human placenta to patients without a prescription when Health Canada has not approved human placenta as a drug;

15. In the alternative, between March 1, 2013 and September 30, 2014 on 85 occasions as Registrant, Manager, Owner and Director you permitted and authorized Support Persons and staff at Marigold to manufacture and dispense drugs containing human placenta to patients without a prescription when Health Canada has not approved human placenta as a drug;

16. Between March 1, 2013 and June 30, 2013 as Registrant, Manager, Owner and Director, you manufactured and dispensed drug product containing human placenta to patients using the name of [redacted], a registered midwife as the prescriber without her knowledge or consent;

17. In the alternative, between March 1, 2013 and June 30, 2013 as Registrant, Manager, Owner and Director, you permitted and authorized Support Persons and staff at Marigold to manufacture and dispense drug product containing human placenta to patients using the name of [redacted], a registered midwife as the prescriber without her knowledge or consent;

18. Between August 1, 2013 and September 30, 2013 as Registrant, Manager, Owner and Director you manufactured and dispensed drug product containing human placenta to patients using the name of Dr. [redacted], a physician registered with the College of Physicians of B.C. as the prescriber without his knowledge or consent;

19. In the alternative, between August 1, 2013 and September 30, 2013 as Registrant, Manager Owner and Director you permitted and authorized Support Persons and staff at Marigold to manufacture and dispense drug product containing human placenta to patients using the name of Dr. [redacted], a physician registered with the College of Physicians of B.C. as the prescriber without his knowledge or consent;

20. Between March 1, 2014 and September 30, 2014 as Registrant, Manager, Owner and Director you failed to cooperate in an investigation conducted by the College pursuant to Part 3 of the *HPA* and Part 3 of *PODSA*;

21. On September 9, 2014 you represented yourself to have qualifications as a pharmacist including that you trained as a "Manufacturing and Formulating Chemist at the University of British Columbia as part of the Manufacturing Pharmacy Residency Program" when the statement was untrue and no such educational program existed.

E. Take Notice that the allegations, if proven constitute offences within the meaning of the *HPA* and *PODSA* as follows:

(i) The offence described in paragraph 1 is a breach of the bylaws to *PODSA* and the *HPA,* and is unprofessional conduct: sections 39(1)(a) and (c) of the *HPA* and section 20 of *PODSA;*

(ii) The offence described in paragraph 2 is a breach the bylaws to *PODSA* and the *HPA,* and is unprofessional conduct and incompetence: sections 39(1)(a), (c) and (d) of the *HPA* and section 20 of *PODSA;*

(iii) The offence described in paragraph 3 is a breach of the bylaws to *PODSA* and the *HPA,* and is unprofessional conduct and incompetence: sections 39(1)(a), (c) and (d) of the *HPA* and section 20 of *PODSA;*

(iv) The offence described in paragraph 4 is a breach of Standards 1, 2, 3, 6, 7, 8 and 9 of the Code of Ethics and is a failure to comply with a limit or condition imposed under the *HPA* and is unprofessional conduct: sections 39(4)(a), (b) and (c) of the *HPA* and section 20 of *PODSA;*

(v) The offences described in paragraph 5, 6 and 7 are a breach of Standards 1, 2, 3, 6, 7, 8 and 9 of the Code of Ethics and are unprofessional conduct: sections 39(1)(a) and (c) of the *HPA* and section 20 of *PODSA;*

(vi) The offence described in paragraph 8 is a breach of the bylaws to the *HPA* and *PODSA* and is unprofessional conduct and incompetence: sections 39(1)(a), (c) and (d) of the *HPA* and section 20 of *PODSA;*

(vii) The offence described in paragraph 9 is a breach of Standards 7 and 9 of the Code of Ethics and is unprofessional conduct: sections 39(1)(a) and (c) of the *HPA* and section 20 of *PODSA;*

(viii) The offences described in paragraphs 10 and 11 are a breach of Standards 1, 2, 3, 6, 7, 8 and 9 of the Code of Ethics and are unprofessional conduct: sections 39(1)(a) and (c) of the *HPA* and section 20 of *PODSA;*

(ix) The offence described in paragraph 12 is a breach of Standards 7 and 9 of the Code of Ethics and is unprofessional conduct: section 39(1)(a) and (c) of the *HPA* and section 20 of *PODSA*;

(x) The offence described in paragraph 13 is a breach of Standards 1, 2, 3, 6, 7, 8 and 9 of the Code of Ethics and is unprofessional conduct: sections 39(1)(a) and (c) of the *HPA* and section 20 of *PODSA;*

(xi) The offences described in paragraphs 14 and 15 are a breach of Standards 1, 2, 3, 6, 7, 8 and 9 of the Code of Ethics and are unprofessional conduct: sections 39(1)(a) and (c) of the *HPA* and section 20 of *PODSA;*

(xii) The offences described in paragraphs 16 to 19 are a breach of Standards 7 and 9 of the Code of Ethics and are unprofessional conduct: sections 39(1)(a) and (c) of the *HPA* and section 20 of *PODSA;*

(xiii) The offence described in paragraph 20 is a breach of Standard 7 of the Code of Ethics and is unprofessional conduct: section 39(1)(a) and (c) of the *HPA* and section 20 of *PODSA*;

(xiv) The offence described in paragraph 21 is a breach of Standards 7 and 9 of the Code of Ethics and is unprofessional conduct: section 39(1)(a) and (c) of the *HPA* and section 20 of *PODSA.*

F. You are entitled to be present and to be represented by counsel at your expense at the hearing. The College will present its case to the Discipline Committee. You will have an opportunity to cross-examine the College witnesses, call evidence on your behalf and make submissions. The Discipline Committee, its counsel, the College Counsel and a Court Reporter will be in attendance. The hearing will be open to the public.

G. Take notice that if you do not attend the hearing, the Discipline Committee may proceed in your absence and may make findings of fact against you and impose a penalty upon you.

H. The *HPA, PODSA, FDA, CDSA, NCR, FDR,* and PPPs are available on the College website at www.bcpharmacists.org/pharmacy-resources.

The *MMPR* and *NHPR* are available at www.CanLii.org.

The NAPRA Guidelines are available at http://napra.ca/Content_Files/Files/Guidelines_to_Pharmacy_Compounding_Oct2006.pdf/.

POL 0051 is available at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol_0051-eng.php.

I. Particulars of the offences are attached to this Citation. With the exception of the cannabis seized from Marigold, all supporting evidence including documents, items, devices, drugs, photographs, digital images and all other evidence in support of the allegations are available for your review and copying by contacting counsel for the College, Ms. Catharine Herb-Kelly Q.C. at the firm of Twining, Short & Haakonson, Suite 500-1122 Mainland Street, Vancouver, B.C. V6B 5L1. Telephone: 604 638 9206. Email: cherb-kelly@tshlaw.ca. The cannabis has been seized by the RCMP and will be presented in evidence at the hearing in cooperation with the RCMP. In addition, if you require hard copies of the legislation referred to in this Citation or the Particulars, please contact Ms. Herb-Kelly Q.C.

Dated this 12th day of October, 2016.

Bob Nakagawa

Bob Nakagawa, Registrar

College of Pharmacists
of British Columbia

PARTICULARS

Particulars regarding the offences set out in the Citation include but are not limited to the following:

1. Isidoro Andres Sanchez ("Sanchez") was at all materials times a full Registrant of the College of Pharmacists of British Columbia ("College"). He was a Director, Owner and Manager within the meaning of the *Pharmacy Operations and Drug Scheduling Act ("PODSA")* of Marigold Natural Pharmacy Ltd., which operated a pharmacy licenced by the College as Marigold Compounding and Natural Pharmacy (collectively referred to as "Marigold") located at 100-576 England Avenue, Courtenay, B.C. ("Premises").

2. Sanchez' registration as a pharmacist and Marigold's license were suspended by the Inquiry Committee pursuant to section 35 of the *Health Professions Act* RSBC 1996 C.183 (*"HPA")* on September 26, 2014.

3. As Director, Owner and Manager, Sanchez failed to comply with obligations in section 3 of the bylaws to *PODSA.* As a Director and Owner Sanchez had a common law and statutory duty to ensure that all pharmacy practices at Marigold were conducted in accordance with the College's bylaws pursuant to the *HPA* and *PODSA*, the *Food and Drugs Act* and *Regulations* thereto, the *Controlled Drugs and Substances Act* and *Regulations* thereto, the College's Professional Practice Policies, standards set by the National Association of Pharmacy Regulatory Authorities ("NAPRA") and by Health Canada, and generally accepted standards of pharmacy practice. He failed to do so.

4. As a Registrant, Sanchez was required to practice the profession of pharmacy, and to ensure that Support Persons within the meaning of *PODSA* and staff at Marigold practiced the profession of pharmacy in accordance with all applicable legislation including the *HPA* and *PODSA*, the bylaws to the *HPA* and *PODSA*, the *Food and Drugs Act* and *Regulations* thereto, the *Controlled Drugs and Substances Act* and *Regulations* thereto, the *Narcotic Control Act* and *Regulations* thereto, the College's Professional Practice Policies, standards set by NAPRA and by Health Canada, and generally accepted standards of pharmacy practice.

5. Sanchez, Support Persons and Marigold staff under Sanchez' direction, failed to comply with the legislation referred to in paragraphs 3 and 4 above on numerous occasions and in many different respects as described in these Particulars.

Failure to Comply with Consent Agreement dated September 14, 2011

6. Sanchez and Marigold were suspended by the Inquiry Committee on June 14, 2010. They entered into a consent agreement with the Committee dated September 14, 2011

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(the "Consent Agreement") whereby their licences were reinstated on terms and conditions including that Sanchez and Marigold would, among other things:

a. Immediately cease manufacturing drugs and refrain from doing so until a Drug Establishment Licence was obtained from Health Canada (Section C.01A.004(a)(1) *Food and Drug Regulations*);

b. Immediately cease manufacturing natural health products (NHPs) and refrain from doing so until a Site Licence was obtained from Health Canada (Section 27 *Natural Health Products Regulations* SOR/2003-196);

c. Comply with the Guidelines to Pharmacy Compounding (2006) endorsed by NAPRA and Health Canada's Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051);

d. Comply with all applicable regulations with respect to dispensing selling, formulating, manufacturing or compounding drugs and natural health products;

e. Comply with the marketing bylaws in Part IX of the *HPA* bylaws;

f. Comply with PPP #58 Medication Management (Adapting a Prescription) and the Orientation Manual and amendments; and

g. Dispense drugs pursuant to valid prescriptions from a prescriber in accordance with Section 9 of *PODSA* and the *Drug Schedules Regulation*.

7. Sanchez and Marigold failed to comply with the terms and conditions set out in paragraphs 6(a) – (g) above.

Manufacturing Drugs and NHPs

8. College inspectors attended Marigold on March 4, 2014 and September 26, 2014. On March 4, 2014, inspectors seized quantities of drugs and NHPs bearing Marigold labels which had been manufactured by Sanchez, Support Persons and Marigold staff. On September 26, 2014 inspectors seized quantities of drugs bearing Marigold labels which had been manufactured by Sanchez, Support Persons and Marigold staff.

9. At all material times neither Sanchez nor Marigold has obtained a Drug Establishment Licence or a Site Licence. Consequently they were prohibited from manufacturing drugs and NHPs pursuant to the applicable federal legislation: Section C.01A.004 *Food and Drug Regulations and* section 27 *NHP Regulations*, and the terms of the Consent Agreement.

10. The Marigold premises included a pharmacy, a compounding room and a manufacturing room for manufacturing drugs and NHPs. There were in excess of 2000 manufactured drugs and NHPs on the shelves in Marigold in the March inspection.

11. At the March inspection approximately 210 NHPs and drugs manufactured by Sanchez and Marigold were seized. Of these, 203 products contained ingredients regulated under the *NHP Regulations* and were therefore NHPs. There were 7 products listing ingredients on their labels scheduled in the *Drug Schedules Regulation* to *PODSA.*

12. At the September inspection, approximately 6000 drugs and NHPs were seized for analysis by the College from Marigold. Eventually the College returned to Marigold's counsel a large number of commercially available drugs so that Sanchez would be able to return them to the wholesalers. The College retained approximately 2000 drugs for the purposes of the Citation. In addition, large quantities of products containing cannabis manufactured by Sanchez and Marigold were retrieved by the RCMP and are still held by the RCMP.

13. The College's position is that the drugs and NHPs seized on both dates had been manufactured by Sanchez and Marigold because, among other things:

    a. They had Marigold labels instead of labels with patients' names;

    b. They were available in bulk quantities rather than specific quantities for a specific patient pursuant to a valid prescription;

    c. Marigold had a low volume prescription count; and

    d. There was no patient-pharmacist relationship with respect to the seized drugs.

<u>Failure to Compound and Dispense in Accordance with Applicable Legislation, Policies & Prescriptions</u>

14. If the NHPs and drugs seized or observed on both inspections were compounded by Sanchez and Marigold, they were not compounded in accordance with PPP #64 which requires all pharmacists to compound in accordance with the NAPRA *Guidelines to Pharmacy Compounding* (2006). Pharmacists are further expected to comply with Health Canada's *Policy on Manufacturing and Compounding Drug Products in Canada* Policy (POL-51), and generally accepted standards of pharmacy practice.

15. Infractions with respect to compounding and the provision of incompetent and unprofessional pharmacy services by Sanchez as a registrant, Manager, Owner and Director of Marigold, and breach of the bylaws include:

a. There were no compounding records or incomplete records in respect of each NHP or drug, contrary to section 7.2 of the NAPRA guidelines.

b. Of the 2000 drugs analysed by the College from the September inspection, 1931 drugs were seized from the dispensary and compounding rooms at Marigold. Over 300 of these drugs had expired, 642 drugs had no expiry date on the label and 893 drugs had excessive expiry dates (total: 1841) (Section 3(2)(h) and section 4(2) *PODSA* bylaws; section 9 *PODSA)*;

c. At the September inspection, loose quantities of Methadone were seized from the Marigold safe including:

i. A quantity of more than 800 capsules of Methadone for patient [redacted] filled in 2009 which should have been disposed of within 6 months of the prescription label date;

ii. A vial of Methadone containing white powder labelled as "Methadone";

iii. A clear Ziploc bag labelled as "Methadone 5mg";

iv. A stock bottle of Methadone Hydrochloride 100g, that had expired September 2012 and was manufactured by Medisca;

(Sections 3(2)(h) and (j) of the *PODSA* bylaws, PPP #65, Schedule F, Part 1, *HPA* bylaws section 9.)

d. The medication refrigerator, a bar fridge in which vaccines were stored, among other things, did not meet the standard for refrigeration in PPP #68 including that it was not monitored and its temperature was outside the acceptable range of 2-8 degrees Celsius;

e. Sanchez and Marigold employees manufactured and/or compounded drugs using hazardous and other substances that must be used only in a sterile environment. There was no section in the Premises that was sterile. Examples of deficiencies in this regard include:

i. The compounding room did not include a certified primary engineering control (PEC);

ii. The PEC did not meet the International Organization for Standardization (IOS) requirements for air quality; and

iii. Sterile products were prepared in an uncontrolled environment that was not in compliance with IOS Standards 7 and 8 increasing the potential for microbial contamination and colonization.

(PPP #64 – NAPRA Guidelines Section 12)

f. 900 of the 2000 drugs seized at the September inspection had excessive expiry dates beyond 2015;

g. Products, including compounded products and ingredients present on the inventory and supply shelves, were missing labels altogether or the labels did not contain the required information for compounding and/or dispensing including strength of ingredient, drug name, drug strength and lot number, quantity of product or medicinal ingredient, expiry date, beyond use date, expiry date of raw materials and directions for use contrary to section 8.2 of PPP #64, section 9(5) of Schedule F, Part 1, Community Pharmacy Standards of Practice, and 7.2.6 of the NAPRA guidelines;

h. Use of expired ingredients and ingredients that were unsuitable for use by reason of their condition evidenced by cracking, mottling, weeping or obvious signs of contamination;

i. Use of uncertified raw materials in the preparation of drug and NHP products contrary to PPP #64 (section 7.1.2) and NAPRA Guidelines to Pharmacy Compounding;

j. Returned drugs were placed in active inventory;

k. Purified water was not used to compound drugs and NHPs ;

l. Hazardous drugs were not stored in accordance with USP Chapter 795;

m. Products containing Schedule II ingredients were present in the professional products area when they should have been in the professional services area – no public access (*Drug Schedules Regulation*);

n. Prescriptions were not filed in compliance with PPP #12 and *PODSA* bylaw section 8;

o. Compounding references and master formulae were not available;

p. Excessive beyond use dating of drugs;

q. Excessively long storage of products on inventory shelves for sale/dispensing;

r. Contaminated, unstable and/or degraded drugs and NHPs manufactured at Marigold were on inventory shelves for sale/dispensing which condition was indicated by cracking, mottling, weeping and use of obviously contaminated materials;

s. Drugs and NHPs were compounded, manufactured and stored in unsanitary conditions;

t. Pre-packed syringes were empty, over-filled, leaking and greasy;

u. No post-production quality assurance evaluation in place;

v. Re-use of bottles, ointment jars and pots intended for single use only;

w. Hydrazine Sulfate, a hazardous substance used for rocket fuel and insecticides, among other things, and disproven as a cancer therapy, was present on the shelves;

x. Failure to protect employees from exposure to bulk active pharmaceutical ingredients;

y. Absence of appropriate written policies and procedures;

z. Failure to preserve confidentiality of patient medication and medical history information regarding patient [redacted]

aa. Failure to refer patients to other health care practitioners for assessment and advice; and

bb. Unconventional pharmacy advice regarding treatment for atrial fibrillation.

16. Sanchez failed to comply with PPP #58 (Medication Management) and sections 25.8, 25.91 and 25.92 of the *HPA,* prescribed prescription medication when he was not authorized to do so; and included false information in patients' PharmaNet records; billed PharmaCare for drugs that were not dispensed, and altered prescriptions without consulting with the prescriber:

a. Dispensed Twinrix to patient [redacted] when a prescription for Havrix had been written by Dr. [redacted] on or about March 4, 2013 without obtaining the informed consent of the patient and without consulting with Dr. [redacted] regarding the adaptation;

b. On or about February 7, 2014, Sanchez compounded Sertraline, a drug used to treat psychiatric illnesses, for patient [redacted] for purposes of titration without a valid prescription;

c. On March 3, 2014 Sanchez dispensed Compounded 5HTP and Levodopa without a prescription for patient [redacted] and submitted to the PharmaNet record that Dr. [redacted] was the prescriber when this was not true;

d. On August 4, 2013, September 14, 2013 and April 16, 2014 Sanchez dispensed compounded "postnatal recovery capsules" to patients [redacted], [redacted] and [redacted] respectively, without a prescription and submitted to PharmaNet that Dr. [redacted] was the prescriber when this was not true;

e. On January 2, 2013 Sanchez compounded and dispensed Testosterone 1% oral gel without a prescription, or alternatively contrary to the prescription for topical Androgel written by Dr. [redacted];

f. On September 13, 2014 and September 19, 2014 Sanchez dispensed compounded cannabis, a non-benefit drug, to patient [redacted] without a prescription indicating in the PharmaNet records that Dr. [redacted] had prescribed the drug on both occasions and that Teva-Nabilone had been dispensed when this was not true;

g. Between July 22, 2014 and September 18, 2014 Sanchez altered instructions for use on prescriptions for Teva-Nabilone prescribed by Dr. [redacted] without her consent for patients [redacted] and [redacted] by instructing the client to double the dose three times per day in the case of [redacted] and take three times per day instead of twice in the case of [redacted];

h. On or about July 22, 2013, October 31, 2013, December 20, 2013 and August 20, 2014 Sanchez dispensed Thyroid to patient [redacted] without a valid prescription and contrary to instructions from the patient's physician, Dr. [redacted];

i. On October 9, 2013 Sanchez dispensed 88 tablets of Desiccated Thyroid to patient [redacted] contrary to the terms of a prescription written by Dr. [redacted] for 60 tablets. Sanchez dispensed 66 tablets of Desiccated Thyroid on December 20, 2013 and 100 tablets of Desiccated Thyroid on February 18, 2014 to [redacted] without a prescription on both dates, indicating in the PharmaNet record that Dr. [redacted] had prescribed the drug which was untrue;

j. On or about January 5, 2013 Sanchez dispensed 100 capsules of compounded Eltroxin to patient [redacted] without a prescription;

k. On or about August 1, 2014, August 8, 2014 and September 5, 2014 Sanchez dispensed 570 capsules of compounded cannabis, a non-benefit drug, to patient [redacted] without a prescription but indicated in the PharmaNet record that the drug had been prescribed by Dr. [redacted] and was dispensed as Teva-Nabilone which was untrue;

l. On or about March 11, 2013 and April 4, 2013 Sanchez dispensed prescriptions for Triest Vaginal Cream to patient [redacted] without a valid prescription and indicated in the PharmaNet record that Dr. [redacted] was the prescriber which was untrue;

m. On or about February 1, 2013, August 23, 2013 and April 9, 2014 Sanchez dispensed Estriol Vaginal Cream to patient [redacted] without a valid prescription and indicated in the PharmaNet record that Dr. [redacted] was the prescriber which was untrue;

n. On or about July 18, 2014 and thereafter on at least one occasion Sanchez dispensed Teva-Nabilone without a valid prescription to patient [redacted] and indicated in the PharmaNet record that Dr. [redacted] was the prescriber which was untrue;

o. On or about August 28, 2013 and September 12, 2013 Sanchez dispensed 500 capsules of DMSA to patient [redacted] without a valid prescription or without obtaining consent of the prescriber to alter the prescription. The prescriber, Dr. [redacted], had prescribed 50 capsules of DMSA on June 28, 2013 with 3 repeats for a total of 200 capsules. Sanchez dispensed 1000 capsules to the patient;

p. On or about June 18, 2014 Sanchez dispensed compounded cannabis oil, a non-benefit drug, to patient [redacted] without a valid prescription and further indicated in the PharmaNet record that the prescriber was Dr. [redacted] and the drug was Cesamet which was untrue;

q. On or about August 14, 2014 and September 3, 2014 Sanchez dispensed 400 capsules of cannabis, a non-benefit drug, to patient [redacted] without a valid prescription and indicated on the PharmaNet record that Dr. [redacted] was the prescriber and the drug was Teva-Nabilone which was untrue;

r. On or about August 30, 2014 Sanchez prescribed and dispensed a compounded ointment containing Ketamine, Amitriptyline, Lidocaine and Lipoderm to patient [redacted] without a prescription, indicating in the PharmaNet record that Dr. [redacted] was the prescriber which was untrue;

s. Between June 1, 2014 and September 30, 2014 on three occasions, Sanchez dispensed compounded cannabis to patient [redacted] when the prescriber, Dr. [redacted] had prescribed Teva-Nabilone;

t. On July 2, 2014, July 25, 2014 and August 12, 2014 Sanchez altered a prescription for cannabis from Dr. [redacted] without his consent or directions for patient [redacted];

u. On or about July 24, 2014 and September 5, 2014 Sanchez altered a prescription for Naproxen Suspension (liquid) by dispensing tablets without the consent of the prescriber Dr. [redacted];

v. On or about March 12, 2103 and September 5, 2014 pursuant to prescriptions from Dr. [redacted], Sanchez dispensed compounded cannabinoid lozenges, a non-benefit drug, to patient [redacted] but billed the prescriptions as Teva-Nabilone and received payment for them from PharmaCare;

w. On or about September 17, 2014, Sanchez dispensed a compounded cannabinoid gel, a non-benefit drug, to patient [redacted] prescribed by Dr. [redacted], but billed the drug to PharmaCare as Teva-Nabilone and received payment therefore;

x. On or about July 29, 2014, August 8, 2014 and August 22, 2014, Sanchez dispensed a prescription for dried cannabis written by Dr. [redacted] to patient [redacted], a non-benefit drug, and billed it to PharmaCare as Teva-Nabilone, receiving payment from PharmaCare therefore;

y. On or about August 22, 2014, Sanchez filled and dispensed a prescription for dried marijuana, a non-benefit drug, to patient [redacted] written by Dr.

[redacted], but billed the drug to PharmaCare as Teva-Nabilone and received payment from PharmaCare therefore;

z. On or about June 19, 2014, July 20, 2014 and September 3, 2014 Sanchez dispensed compounded cannabinoid capsules, a non-benefit drug, for patient [redacted] pursuant to prescriptions from Dr. [redacted], but billed the prescriptions to PharmaCare as Teva-Nabilone and received payment from PharmaCare therefore;

aa. Sanchez dispensed prescriptions for Progesterone and Biest to patient [redacted] without a valid prescription therefore in the name of Dr. [redacted] on May 20, 2014, and August 18, 2014, pursuant to prescriptions written by Dr. [redacted] without his approval and when he had only written a prescription for these drugs on March 12, 2014;

bb. Sanchez dispensed cannabinoid capsules, a non-benefit drug, pursuant to a prescription by Dr. [redacted], to patient [redacted] on or about July 8, 2014 but billed the drug to PharmaCare as Teva-Nabilone and received payment from PharmaCare therefore;

cc. Sanchez dispensed cannabinoid capsules, a non benefit drug, to patient [redacted] pursuant to prescriptions from Dr. [redacted] on or about March 3, 2014, April 22, 2014 and May 23, 2014 and billed them as Cesamet to PharmaCare and received payment therefore from PharmaCare;

dd. On or about May 29, 2014 Sanchez dispensed compounded Folic Acid pursuant to a prescription from D. [redacted] when Folic Acid is commercially available;

ee. On or about June 12, 2014 Sanchez dispensed Desiccated Thyroid to patient [redacted] without a valid prescription (renewal) from Dr. [redacted];

ff. On or about July 6, 2014 Sanchez dispensed Synthroid to patient [redacted] without a valid prescription (renewal) from Dr. [redacted].

Unprofessional Conduct (does not exclude conduct referenced elsewhere in this document)

17. On July 9, 2013, College inspectors Nikkel and Graves attended Marigold to conduct an inspection. They documented deficiencies which were brought to Sanchez and Marigold's attention in an Inspection Reply Form (IRF). On August 9, 2013, Sanchez returned the IRF to the College indicating the deficiencies had been corrected when this was not true. At the March 4, 2014 and September 26, 2014 inspections, ongoing

deficiencies identified in the IRF and said to have been corrected by Sanchez were observed including:

a. The refrigerator was not in compliance with PPP #68 and was not suitable for storing biologicals;

b. Marigold did not have a traceable memory thermometer;

c. Narcotics and narcotic compounds were not being counted and reconciled;

d. Compounding logs were incomplete or did not exist;

e. Labelling on drugs and NHPs was incomplete, inaccurate or missing altogether;

f. Expiry dates were inappropriate or beyond use: Health Canada POL-51, USP 795 Pharmaceutical Compounding – Nonsterile Preparations and ISMP-Canada Quality and Safety in Compounding Non-sterile Preparations Report, Appendix M;

g. There was no documentation to show that IOS standards were met;

h. Expired commercial and compounded products were present on the shelves;

i. Prescriptions were not filed properly in accordance with PPP #12 or were not filed at all: section 8(1)(a) bylaws to *PODSA* – including that they were not organized by date or by sequential prescription or transaction number; they were not filed by date ranges; controlled drug substance prescriptions were not filed separately from Schedule F drug prescriptions;

j. 15 drugs seized in March and September, 2014, were waiting for pick up and were not reversed after 30 days – section 21(5) *PODSA* bylaws;

Breach of Legislation and Unprofessional Conduct – Manufacture & Dispensing Cannabis

18. At the September inspection, College inspectors seized products containing cannabis. These products were delivered to the RCMP.

19. Neither Sanchez nor Marigold are licensed producers within the meaning of the *Marihuana for Medical Purposes Regulations* nor are they licensed dealers pursuant to the *Narcotic Control Regulations.*

20. Marigold and Sanchez, Support Persons and Marigold staff manufactured and dispensed products containing cannabis. In addition to their failure to obtain the requisite licenses, they manufactured these products contrary to the applicable legislation because they were in many forms such as liquid, capsules, cookies, oils, lozenges and patches. At the material time, the only form of cannabis that may be dispensed pursuant to a valid prescription in accordance with the applicable legislation is dried.

21. Sanchez dispensed cannabis to patients without valid prescriptions (see paragraph 16 subsections f, g, k, n, p, q, s, v, w, x, y, z, bb and cc above).

22. Sanchez and Marigold processed over 250 drug orders on the PharmaNet database containing cannabis between January 1, 2013 and December 31, 2014. Of these 250, the majority were not dispensed pursuant to a valid prescription from a physician, with the exception of prescriptions obtained from Dr. [redacted].

23. Sanchez submitted unlawful billings to PharmaCare for drug products containing cannabis for which he and Marigold were paid $25,542.06 from PharmaCare. The billings to PharmaCare were for commercially available drugs containing cannabis and approved by Health Canada known as Cesamet and Teva-Nabilone, but Sanchez in fact dispensed products compounded or manufactured by him and Marigold.

Breach of Legislation and Unprofessional Conduct – Placenta Encapsulation, Failure to Cooperate

24. Sanchez and Marigold manufactured and/or compounded drugs containing human placenta within the meaning of section C.01A.004 of the *Food and Drugs Regulations.* They did not have a Drug Establishment Licence. Human placenta has not been approved for use in Canada and does not have a Drug Identification Number. Currently, it cannot be dispensed, compounded, manufactured or prescribed anywhere in Canada.

25. Between January 1, 2013 and December 31, 2014, Sanchez and Marigold manufactured or compounded and dispensed 88 "orders" for placenta to patients. Drugs containing placenta seized by College inspectors were contained in bottles bearing Marigold labels.

26. Sanchez admitted to Inspector Pollock that he encapsulated placental tissue for mothers' consumption upon request from a mother or midwife, and that he received placenta for this purpose from mothers shortly after birth.

27. On 7 of these occasions, Sanchez indicated in the PharmaNet records that placenta had been prescribed by two practitioners, namely [redacted], a registered midwife and Dr. [redacted], a physician, when they had not prescribed placenta.

28. Otherwise Sanchez described himself as prescriber – he is not a practitioner and is not authorized to prescribe. Accordingly all 88 "prescriptions" to patients were illegal and contrary to section 9 of *PODSA,* sections 4(5) – 4(7) of the bylaws to *PODSA.*

29. College inspectors requested information from Sanchez as the March and September investigations progressed. He failed to reply at all, or provided non responsive and/or inadequate responses:

    a. Email to Sanchez March 18, 2014 from Esther Jeon including 5 questions from Inspector Pollock. A reply was received dated March 26, 2104 but it was non-responsive. Inspector Pollock sent Sanchez further questions by letter dated April 28, 2014. The deadline for his response was May 8, 2014, but no reply was received;

    b. Ms. Jeon and Inspector Lau requested responses to a letter dated March 21, 2014 by email dated April 8, 2014. The deadline for response was April 25, 2014. No response was received.

    c. Inspector Graves requested further documents from Sanchez by letter dated April 8, 2014. The deadline for response was April 21, 2014 but no response was received.

    d. Ms. Jeon sent Sanchez letters dated November 21, 2014 and December 23, 2014 with requests for information about his manufacture and dispensing of products containing cannabis, among other things. The deadline for response was December 5, 2014 and January 8, 2014 respectively, but no response was received.

    e. Ms. Jeon sent a letter to Sanchez dated January 5, 2015 with further questions about compounding with a deadline for response of January 12, 2015, but no response was received.

    f. On or about March 4, 2014 Sanchez advised Ms. Jeon and Inspector Pollock that he and/or Marigold had received permission from Health Canada to manufacture drugs and NHPs on an interim basis, without the requisite licenses, when this was not true.

<u>Unprofessional Conduct - Misleading Advertising</u>

30. Sanchez misrepresented his educational qualifications as a pharmacist on the Marigold Compounding and Natural Pharmacy website on September 9, 2014 when he stated that he "trained as a Manufacturing and Formulating Chemist at the University of British Columbia as part of the Manufacturing Pharmacy Residency Program." No such

program existed at the time he was a student at UBC nor has such a program ever existed. Sanchez obtained a Bachelor of Science in Pharmacy in [redacted].

31. Sanchez advertised on the Marigold website, among other things, that placenta has healing properties, including but not limited to that it allows restoration of hormones to normal levels, prevents mood swings and post-partum depression, restores thyroid stimulating hormone, protects against infections, increases energy levels and increases breast milk production. These claims are unsubstantiated and contrary to section 9(1) of the *Food and Drugs Act.* Sanchez further advertised that the compounding process of placenta encapsulation occurred in a sterile laboratory when Marigold is not a sterile environment. These representations constitute a breach of the Consent Agreement wherein Sanchez and Marigold agreed to comply with the College bylaw on marketing in Part IX of the *HPA* bylaws.