

# Vital Link

The journal of the Canadian Association of Naturopathic Doctors

## Feature Articles

- 🔥 **Scope of Practice:  
The Determinants of  
Possible Change**
- 🔥 **Prescribing in BC:  
A Snapshot History**
- 🔥 **Ontario Regulations —  
What Has Changed,  
What's To Come**
- 🔥 **Natural Hormone  
Prescriptive Authority for  
Naturopathic Doctors: a  
Discussion**
- 🔥 **Naturopathic Doctors;  
Primary Care Practitioners  
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Volume 24, Issue 3

Winter 2018



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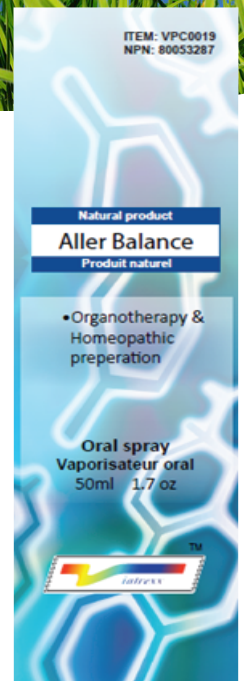
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# Vital Link

The journal of the Canadian Association of Naturopathic Doctors

Volume 24, Issue 3, Winter 2018

Prescriptive Authority for Naturopathic Doctors

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The *Vital Link* is the journal of the Canadian Association of Naturopathic Doctors (CAND). It is published primarily for CAND members and features detailed reviews of specific causal factors of health and disease, philosophical and research-based papers, clinical practice articles and case reviews, and international updates on the naturopathic profession.

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**Spring 2018** Case Reviews: Acute Mental/Emotional Health

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# Naturopathic Notes

Dr. Iva Lloyd, BScH, ND

The addition of prescriptive authority to some Canadian jurisdictions has changed the naturopathic conversation. British Columbia received prescribing access in 2015. Ontario followed, with a narrower prescribing scope, in 2017. Currently, the Profession in Alberta is also seeking prescribing access. Some naturopathic doctors are against naturopathic prescribing, while some see it as an advancement of our profession, and others are just not sure.

**W**e trust that the articles in this *Vital Link* will shed some light on prescribing and will constructively add to the prescribing conversation.

Dr. Christoph Kind, ND from British Columbia who was actively involved in lobbying efforts, and Glenn Cassie, Executive Director of the BC Naturopathic Association provide an overview of the prescribing process and status in BC. They take us through the dedication and work that went into BC NDs' acquiring such broad access to prescribing.

I have found over the years many people do not understand the lobbying or prescribing process in Canada. Readers of my article, *Ontario Regulations – What Has Changed, What is Yet To Come*, will find a detailed overview of the prescribing process in Ontario, a highlight of what access we currently have and a listing of the substances that are currently being considered for addition. You will also find a chart summarizing the scope of practice of all the regulated jurisdictions in Canada and the U.S.

For years Dr. Paul Saunders has been involved in government relations and in lobbying efforts for the naturopathic profession. Paul's editorial provides an overview of his perspectives and his hope for the Profession moving forward.

Prescribing access has provided naturopathic doctors in British Columbia and Ontario the ability to prescribe bioidentical hormones. Dr. Joël Lee Villeneuve, ND provides an overview of how these hormones have expanded naturopathic practice and the added benefits to patients of our ability to prescribe hormones. Drs Tara O'Brien, ND and Alan Price, ND provide a detailed look at the history and therapeutic role of desiccated thyroid hormone, and thyroid dysfunctions.

I hope you will benefit from, and enjoy this edition of the *Vital Link*. In forthcoming editions we will share research and case studies about a number of naturopathic topics.

To digress, this issue represents a bittersweet change for the *Vital Link* team. Longtime *Vital Link* reviewer, Dr. Dugald Seely, ND, MSc, will be stepping away from our review team as Dugald tends to his many duties, including his roles as a researcher, and the executive director of the Ottawa Integrative Cancer Centre. Dugald: for more than ten years you have provided such strong support in assisting the CAND improve the quality of the journal, and we have enjoyed having you as part of our editorial team. The *Vital Link* will miss your input.

To all our readers: thank-you for your support of the *Vital Link*. We welcome your feedback and suggestions. 🍂







# Scope of Practice: The Determinants of Possible Change

Dr. Paul Richard Saunders, PHD, ND, DHANP

Naturopathic medicine in North America owes its existence to the vision and determination of our elders for a medicine that encompassed the whole individual, was not limited by single modalities, and involved patients in their own care.

Today our challenges include an evidence-based rather than evidence-informed approach to health care, a more youthful profession with less life experiences, a greater diversity of scopes, and a society focused on stricter regulation of our activities of daily living. Our graduates face significant, even crushing debts, and the challenge of establishing themselves and their practices in cities where earlier graduates are struggling to stay afloat.

“Scope of practice” is the legal term that describes what a health care provider can do for their patients in any given jurisdiction. The elements that culminate in a defined scope of practice include: the education of the health care provider; the specific values and skills sought by the association that represents those health care providers; the political pressures brought by the ministry of health and other regulated professions, and the degree to which the regulatory college supports both the provider’s educational skill set, and the aspirations of the representing association.

Educational institutions through their curriculum and research initiatives can grow or curtail their graduates’ skill set. Bold actions, such as reducing curriculum hours, making required competencies electives (note: there is a recent example where a competency was essentially made unavailable to the majority of students), and/or giving a greater voice to faculty who arbitrarily oppose certain practices could have negative consequences. Perhaps the greatest concern is that a prominent, yet arbitrarily negative opinion about a long-used naturopathic modality or practice could mislead naturopathic students as to what is or is not to be considered an example of good science or practice. Homeopathy and manipulative therapies are but two examples of long-used, safe, and effective practices that some naturopathic programs are questioning or seeking to reduce. The process is based on the opinions of a few stakeholders, who may either have limited clinical experience or may fear the conventional medical world’s opinions of said modalities.

In our small profession some educational programs have relied on less experienced graduates modelling for the novice doctor rather than seeking out the clinical experience of those who have multiple decades of practice on a diverse group of patients, and their varied conditions. To be fair, the experienced physician should be presenting, writing or otherwise detailing what they have observed and learned. Some cultures and some forms of medical practice venerate and choose to learn from their elders. However, at this time when evidence-based-medicine is fashionable few have chosen to let clinical experience inform their clinical decision-making, instead allowing the *p* value, or the absence of a study, decide what they write on their script pad.

A naturopathic medical student’s education and clinical knowledge will increase with time, and have the potential to affect the breadth of their individual practice focus. Without our elders examining the broader fields of medical practice and contemplating how these could assist naturopathic doctors to help their patients, our profession would not be able to today perform a great number of assessments and treatments; these include the provision of: methylcobalamin and folic acid injections; laboratory testing to determine whether a particular patient would need that intramuscular injection; IV therapies of vitamins, minerals, amino acids, cofactors and botanicals for depleted or compromised patients; a broader range of manipulative and musculoskeletal therapies for patients with specific physical needs; or orthomolecular doses of vitamins, minerals and cofactors to meet the unique biochemical needs of some patients (which is often based on laboratory testing). Historically, the naturopathic profession in Canada has been able to integrate new medical knowledge and therapies. It will be interesting to see how the future unfolds in that regard.

Yet another player in determining the profession’s of scope of practice is the provincial/territorial association. The association through its leadership can and should provide a concise, targeted message when scopes of practice are discussed. When the association has little direction, does not work with the other stakeholders, or sends the wrong message (or no message), this can have adverse effects on scope. The recent successful regulation of traditional Chinese medicine and homeopathy in Ontario demonstrates how focused efforts have brought barely a few hundred practitioners together, given them legal status, regulatory colleges, and access to the pot of limited extended health-care dollars.

Scope of practice is unfortunately also a product of the provincial



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and federal political process, which often involves entities who take on a larger role than the lives of the patients they claim to protect. Checks and balances are hoped for in the political process, but we can all think of past and recent examples where larger stakeholder groups have dictated the outcome without respect for the smaller players or have used the smaller players for their own political gain. Thus, it is imperative for the education and association organizations to work together with a well-thought-out plan of both message and threading their way through the politics of regulation.

Regulatory colleges have the important legal obligation of public protection. If the messages from the educational institutions and/or provincial/territorial associations do not demonstrate and reiterate how their proposed changes will better protect, i.e. care for the public, then scope discussions are often doomed. Cooperation by all is essential. Taking sides and ego need to be set aside for the common good of the patient and public, and for the health of the profession. Regulatory colleges must also be willing to engage both the other colleges and the health ministry for scope changes to be positively adjusted.

Last, but not least, it is up to the individual naturopathic doctor to be up-to-date in their clinical skills and scope of practice. This means: reading journals on a regular and ongoing basis; taking quality continuing education courses that advance skill-sets; applying newly acquired knowledge to patients in need; being willing to think outside of the box; and recognizing the value of a broad scope of practice. It is also important for naturopathic doctors to participate in provincial and national associations and to support the missions of their associations. It is through the work of the naturopathic associations than an individual ND's voice can be heard.

Naturopathic medicine was founded and advanced by such individuals as: Father Sebastian Kneipp, who ministered to both souls and bodies despite the admonitions of the Church; Benedict Lust who learned from Kneipp and brought that message to North America despite life-long persecution from the American Medical Association; Henry Lindlahr who founded education programs and added to his scope of practice new tests and treatments that he found beneficial; John Bastyr who combined herbal, homeopathic, and manipulative knowledge to care for young expectant mothers, their newborns, and other patients; and John Uri Lloyd who took the experiences of native healers and practicing doctors to develop better, more effective herbal extracts to address the challenging illnesses of his era. Let these and the many other pioneers of our medicine be an inspiration to you, not only in clinical practice, but also outside the clinical setting, where you may devote your time and effort to helping shape an environment in which the naturopathic profession can thrive and expand.

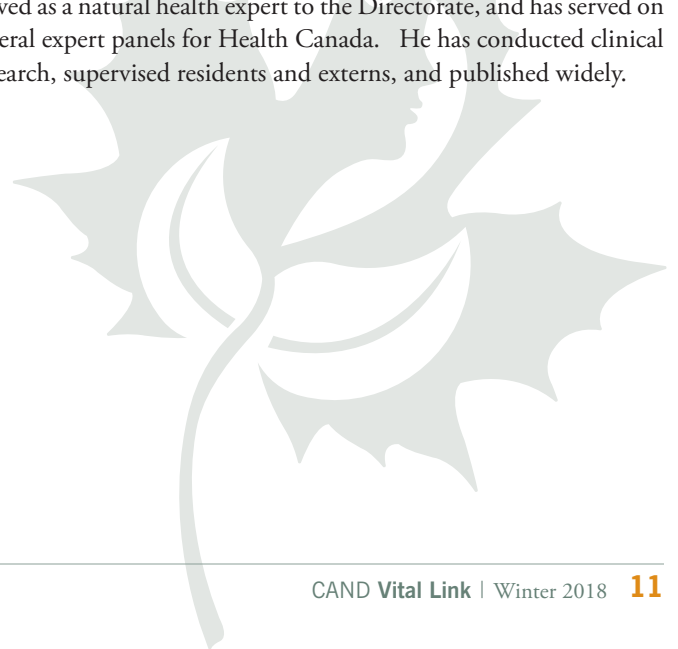
Naturopathic doctors in Canada are primary care practitioners, and regardless of scope of practice, our ultimate goal should be to provide patient care to the highest level possible. Although, for example, prescribing in British Columbia has a broader meaning for

NDs than it does in Ontario, in both provinces the focus of NDs should be to both test and prescribe appropriately for each patient who presents in need.

In British Columbia 77% of naturopathic physicians have their prescribing license while in Ontario only 38% have theirs. It is disappointing to think that there are NDs in our profession who seem willing to rest on the laurels of our predecessors rather than ascribing and fulfilling the available scope. Naturopathic doctors in all jurisdictions should both practice to their full scope and seek to match the fuller scope of other jurisdictions. Primary care practitioners such as naturopathic doctors cannot provide safe and effective care if they do not keep up-to-date, do not practice to their full scope, and do not seek to keep that scope alive and nurtured. Look at your challenging and unsuccessful primary care cases and ask yourself, "What tools do I need to assist this patient in their healing process?" Identify your needs; prioritize them, discuss them with our colleagues and associations, and then work to achieve them. Make this your dream and it can be accomplished sooner than you think. 🍂

### About the Author

**Dr. Paul Richard Saunders, PHD, ND, DHANP** earned his PhD at Duke University in forest ecology, his ND at Canadian College of Naturopathic Medicine and completed residency at National College of Naturopathic Medicine, Portland, Oregon, earning a second ND. He is Professor of Materia Medica and Clinical Medicine at the Canadian College of Naturopathic Medicine; Senior Naturopathic Doctor, Beaumont Health System, Troy Hospital, Michigan; Adjunct Professor of Integrative Medicine Oakland University, William Beaumont Medical School; Professor of Homeopathy at the Canadian College of Homeopathic Medicine, Toronto; and has a private practice in Dundas, Ontario. Paul was a member of the transition team that formed the Office of Natural Health Products, served as a natural health expert to the Directorate, and has served on several expert panels for Health Canada. He has conducted clinical research, supervised residents and externs, and published widely.





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# Prescribing in BC: A Snapshot History

Dr. Christoph Kind, ND

For the best part of a decade, licensed naturopathic doctors in BC have been prescribing scheduled drugs safely, effectively, and when appropriate. For new graduates, and perhaps doctors transferring from some American jurisdictions, it may seem like the status quo. But the process to enable prescribing authority occurred over decades, entailed an enormous amount of effort on behalf of the profession, often the public as well, and in the end depended on the good will of a government committed to ensuring licensed practitioners provided health care commensurate with their training, education and experience.

The struggle, if you will, to access medicines relevant to primary care, has a long history. However, the most significant dates that allowed for a framework to prescribe were in 2008 and 2010. In 2008 the BC government Throne Speech spoke to health providers utilizing their full scope of practice and expertise. In respect to this profession, their commitment read “Naturopaths will be permitted to prescribe medicinal therapies as appropriate and restrictions on their access to medical labs for prescribed tests for patients will be removed.” Then, in the spring of 2010, the regulatory college established the *Standards, Limits and Conditions*, or SLC document, a template for the educational upgrade and ongoing provision of scheduled drugs. As with the entire process, this was also a collaborative effort, involving health professionals from different disciplines and the support of other colleges.

Finally, in the fall of 2010, health in BC took an enormous leap forward: Licensed naturopathic physicians, who chose to obtain prescribing authority, were granted access to a wide range of therapeutics previously limited by prescription. This enhanced the existing care NDs currently provided, while improving primary care options across the province.

2010 was a pivotal year for the profession, not simply in terms of prescribing, but regaining lost ground in terms of care. Although

licensed as doctors in BC since 1923, originally in an omnibus bill encompassing “allopaths, naturopaths and osteopaths,” it was 1936 when distinct legislation for naturopathic physicians was formally enacted. Since then, however, many traditional medicines once available to NDs, as well the ability to compound and prescribe, were gradually and increasingly restricted. It was 1958 when the provincial government established a legislative mandate to enact a defined schedule of preparations for NDs. But that commitment lagged in legislative limbo for many years—even though a formal “*materia medica*” had been completed in 1979 and a tentative governmental commitment to act on the mandate was made at the start of the 1990s.

Despite these many setbacks there was always a focused determination and dedication amongst NDs; the collective efforts of many, over many years, involving letters, meetings, presentations, solicitation and eventually even public outcry, brought the issue to the fore.

I was licensed in BC in 1986. At the time there was slow but forward movement with government. A commitment by Elizabeth Cull, who in the early 90s was the BC Minister of Health, led most of us to believe we had finally secured prescribing authority. Sadly, that commitment died in cabinet. Then, shortly afterwards, the NDP government initiated reviews of all licensed health professionals; one part of the review examined scope of practice, the other legislation. This essentially stalled all licensed health professions from advancing their objectives for over six years.

During the review years, our regulatory board decided it was in the interest of the profession to voluntarily move under the umbrella legislation, the Health Professions Act; the ANPBC became the CNPBC during this time. That effectively ended our legislative review, but our scope review continued, and we petitioned vigorously for prescription rights (among many other aspects of care—the scope review put the whole profession up for new limits and conditions). The scope review began under BCNA President Dr. Eugene Pontius, and continued under his successors, Drs. Braven Rayne, David Wang, Garrett Swetlikoff and eventually myself.

The Health Professions Council, overseeing the review process, published first a preliminary and then some months later a final report on our scope—or at least their recommendations for NDs in the future. The difference between the two was quite radical; the preliminary was far from perfect but it was progressive, the final limiting, regressive. In fact, the final report nearly derailed

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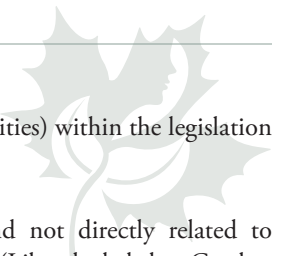
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the profession with stagnant, uninformed and often biased views on integrative care. Worse, it provided no sources or substantive reasoning for its recommendations (when BCNA requested the supporting material used by the Council to arrive at its recommendations, government informed us they did not have any such material and, as the Council had disbanded, there was no archival material to provide). The preliminary report was published at the end of 1998. Based on the Council's comments, BCNA responded with a huge volume of citations and research material to address the shortcomings. At the time, 15 health professions were reviewed in respect to scope; for 14, there was little or no change to the preliminary and post-hearing reports. In our final report there were many significant changes, none of our submissions had been considered or reviewed; allergy challenge testing was modified, laboratory testing was limited, and the Council stated they were "not satisfied that naturopathic physicians are trained and educated to use the proposed Schedule 1 substances, nor is it satisfied that the use of these substances is related to the practice of naturopathic medicine."

Despite the many years of negotiation with the Council, research, correspondence, testimony and negotiation, it was virtually for naught; members had to regroup and refocus our efforts to survive as a viable health profession.

We were fortunate that with the support of our patients, and with the extensive research collated during the review years, we had a strong case to move forward on scope issues and to question the legitimacy of the review process and outcome. At a meeting with the Deputy Minister, during which BCNA President Dr. Garrett Swetlikoff and myself attended, we were able to argue for the ministry to more fully examine these outstanding issues. This led to an independent health audit being commissioned by the ministry in 2003. This was the first time in the history of the profession in BC where government supported, and paid, for an independent audit in respect to our scope. In late 2004, the Naturopathic Scope of Practice Gap Analysis was completed. Just as in decades past, a huge number of NDs across the province, from the professional and regulatory boards, and members at large, came together to help support the analysis.

The Gap Analysis examined the prejudice which arose from the scope review. It outlined the historical and contemporary practice of naturopathic physicians in BC and set forth a framework to achieve a practice commensurate with the education, training and expertise of our members. The regulatory college was able to demonstrate, for example, that for many years the standards they had established for invasive therapies had shown competency and breadth of care amongst the profession—without significant safety issues. One of the most important aspects of the Gap Analysis was that it examined BCNA submissions countered with the Council's mandate. The threshold for granting a reserved act, such as prescribing, was whether the profession can apply the therapy without risk to public safety. In virtually all the reserved acts, the Gap Analysis showed clearly that the HPC had not acted within its mandate when the final report was published. The Gap Analysis was integral to establishing additional

reserved acts (now termed restricted activities) within the legislation for licensed NDs.

Concurrent with the Gap Analysis, and not directly related to the profession, the new government (Liberal, led by Gordon Campbell) launched a process called the Conversation on Health Care, a province wide dialogue on the future of health in BC. We encouraged doctors, patients and those familiar with the profession to get involved. We developed messaging, provided members with postcards and patient information, and tried to get NDs into each and every town hall event province wide. The outcome of the process served the profession very well: Overwhelmingly British Columbians expressed their desire for choice and meaningful access to complementary and preventive health care.

While I had worked with Dr. Swetlikoff as BCNA Vice-President, in 2007 I assumed the President's role at BCNA. The effort the BCNA took in those years in respect to the Gap Analysis and Conversation consumed almost all of the executive's attention. It was a time of arduous politicking and extensive travel and meetings. However, I firmly believe that the determined efforts by both the professional association and regulatory board on behalf of the profession, which culminated in the Gap Analysis and involvement with the Conversation, were key to establishing prescribing authority. The collaboration of doctors, the support from those outside the profession, and the clarity of our collective vision, led to the Throne Speech commitment in 2008—and this, once and for all, made clear government's support and commitment to recognize the value of naturopathic medicine in BC and bring resolution to what had been in limbo for decades.

It would be impossible to individually thank the people who helped bring us to that significant turning point: The doctors who so tirelessly campaigned during the 1970s and 80s when the profession was but a few dozen strong; those who contributed to research, writing, meetings and speaking with ministers, to panels, bureaucrats; the many doctors on boards and committees who built on the work that had been established by our elders. It is most important, however, to note that without a concerted and combined effort during the review years, of both our professional and regulatory boards, to advance the profession, our efforts would have been in vain.

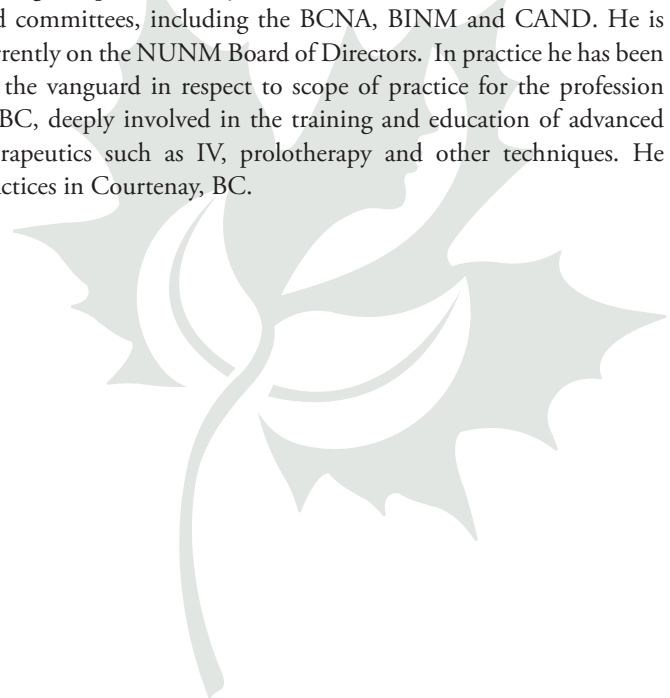
From my perspective, having been on the BCNA Board of Directors during those significant years, the success was tempered by many setbacks. We had to argue with great persuasion to access many botanical medicines, natural therapeutics and other traditional items which, over time, had become scheduled and therefore inaccessible to NDs. If there was a bright side to it all, it was perhaps that the protracted negotiations gave us an opportunity to enlighten and educate politicians, their staff, and other key health professionals on the education and training of NDs—and the substantial contribution NDs make to health care in the province. The years of negotiation on scope actually helped the profession create a political identity that it lacked in the past.

Underscoring how prevention and treatment of physical and mental disease, disorders and conditions is at the heart of primary care, and of course the extensive depth of naturopathic care, was actually a revelation to many! It was also a complex issue to explain that NDs would be offering prescriptions when appropriate, that access to drugs wasn't about a departure from current practice but more a reflection of the expertise of NDs and streamlining the delivery of primary care. Most importantly, an ND in BC with prescribing authority has full access to natural medicines previously held behind locked doors.

The ability to prescribe has enhanced the provision of naturopathic medicine in unquantifiable ways: it was a landmark in provincial and Canadian health care as it marked a fundamental shift towards better patient options, enhanced choice in primary care and set a benchmark for other provinces. From my personal point of view, it wasn't an expansion of scope of practice, as was the opinion of the Health Professions Council, but rather recognition of what NDs already do. Having said that, as a doctor in his third decade of practice, I feel we need to remember that prescriptive authority is a facet of our care, not the defining element. I am disheartened to see new doctors being tempted to reach for a scrip pad when there are so many botanicals and traditional remedies that have stood the test of time and work so effectively and demonstrably. One of the most relevant features of attaining prescribing in BC was the "historical use" appendix in the SLC document; this enshrines access to scheduled botanicals, vitamins, minerals and amino acids, core elements of our everyday practice. 🌿

## About the Author

**Dr. Christoph Kind** completed undergraduate studies at the University of Victoria, then his ND at National College, now NUNM. He has been in active practice in BC since 1986. During his professional years he has served on numerous boards and committees, including the BCNA, BINM and CAND. He is currently on the NUNM Board of Directors. In practice he has been on the vanguard in respect to scope of practice for the profession in BC, deeply involved in the training and education of advanced therapeutics such as IV, prolotherapy and other techniques. He practices in Courtenay, BC.



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# Ontario Regulations — What Has Changed, What's To Come

Dr. Iva Lloyd, BScH, RPP, ND

The naturopathic profession in North America has the most comprehensive regulation, training and scope of practice of any region, worldwide. In fact, Canada has the highest number of regulated naturopathic doctors per capita globally with Ontario leading the pack.

When Ontario first regulated naturopathic doctors (NDs) in 1925 under the Drugless Practitioner's Act (DPA), the regulations were broad and stated that NDs could practice what they were taught.<sup>1</sup> The regulations were scant in details – as were most regulatory documents for health-care professionals at that time. Ninety years later the regulatory process is very different, especially since the introduction of the Regulated Health Professions Act (RHPA) which came into effect in 1991.<sup>2</sup> Naturopathic regulations in Ontario are now intertwined with a number of legislative acts including the Laboratory and Specimen Collection Centre Licensing Act, Drug and Pharmacies Regulation Act, Corporations Act, as well as regulations for chiropractors, traditional Chinese medicine practitioners and others.<sup>3</sup> Acquiring regulatory status or changes in scope is a delicate dance, involving many stakeholders and many different points of view. All of that being said, we have a lot – an awful lot – to be proud of in Canada, especially in Ontario. Ontario NDs are deservedly recognized as primary care practitioners and we have one of the broadest naturopathic scopes in Canada.



To learn more about the history of the naturopathic profession in Canada and the regulatory process, refer to the book, *The History of Naturopathic Medicine, a Canadian Perspective*.

Since our initial regulation in 1925 there have been six significant regulatory 'battles' in Ontario. The first in 1944, then 1952, 1961, 1966, 1983 and 1990.<sup>4</sup> Each time there were dedicated naturopathic doctors that put in many, many hours to safeguard the practice of naturopathic medicine. Their efforts moved us forward and secured a stronger foothold for our profession. We did not always acquire what we strived for, but we maintained our regulatory status and over the years the profession blossomed, and scope expanded. Although the naturopathic profession was regulated in Ontario, they were the only regulated health professionals, not brought under the RHPA when it was enacted in 1991. In 2006, Angela Moore ND, who at the time was

the Chair of the Board of Directors of Drugless Therapy – Naturopathy (BDDT-N), notified the Ontario Association of Naturopathic Doctors (OAND), the Canadian Association of Naturopathic Doctors (CAND) and the Canadian College of Naturopathic Medicine (CCNM) that either we should take the steps to move under the RHPA or lose our regulatory status as the government indicated it intended to 'sunset' the Drugless Practitioners Act. That marked the beginning of the nine-year journey (many would call it a battle) for inclusion and regulation under the RHPA. The profession's quandary was how to fit their existing scope within the confines of the RHPA. There were some casualties (such as the loss of mesotherapy) in the process, but overall the profession came through stronger and was for the first time, in a long time, on an equal footing with other primary health-care professionals in Ontario.

The advantage that naturopathic doctors had when regulated under the DPA was that the "scope" was based on what was taught in the accredited naturopathic curriculum.<sup>1</sup> Thankfully for the naturopathic profession, broad wording of scope was common in early regulatory documents. This allowed health-care professions some latitude in how they practiced.

The main reason NDs in Ontario have laboratory access, and can perform IV therapy and vitamin B12 injections is because naturopathic doctor Paul Saunders recognized an opportunity, and worked with CCNM to have all three items included in the curriculum, and the OAND to train practicing naturopathic doctors in intramuscular injections, phlebotomy, and laboratory testing and interpretation. CCNM at that time was helping the profession in Ontario expand its scope offering patients a broader list of treatment options. Once NDs were taught a skill, they were able to practice it. At that time, it was a bit of a chicken-and-egg scenario; a health-care profession can't get access to controlled acts until it has the appropriate education and until it demonstrates competency; however, our profession can't justify including a subject in the naturopathic curriculum or demonstrate competency until it has access.

Choosing not to move under the RHPA was not an option, as there were many disadvantages to the DPA. The DPA didn't serve the public or the profession well, especially with respect to unregulated 'copycat' practitioners. That being said, the BDDT-N did a great job in balancing their responsibilities to the public and the profession with very little to work with. Naturopathic doctors Angela Moore and Pat Rennie served as Chair of the BDDT-N from 1993 – 2007 and 2008 to 2015, respectively. Under their guidance and with the support of their respective boards, they truly safeguarded our profession through the years of very difficult times politically. Our profession owes a huge debt of gratitude to the time and attention that they both gave. The previous BDDT-N chair, Jim Spring, ND put Ontario under NPLEX which helped CCNM achieve CNME accreditation.

Below is a synopsis of how the new prescribing and laboratory access in Ontario has affected naturopathic practice. In the context of the history of our profession, it is clear we have a lot to be proud of in Ontario and in Canada.

### Controlled Acts in Ontario

There are 14 controlled acts under the RHPA.<sup>2</sup> Naturopathic doctors in Ontario were granted the following six controlled acts:

1. Communicating a naturopathic diagnosis;
2. Performing a procedure below the dermis;
3. Moving the joints of the spine beyond the individual's usual physiological range of motion using a fast, low amplitude thrust;
4. Administering a substance by injection or inhalation;
5. Putting an instrument, hand or finger beyond the labia majora but not the beyond the cervix and beyond the anal verge but not beyond the rectal-sigmoidal junction;
6. Prescribing, dispensing, selling or compounding a drug.

Other rights that we have under regulation include the protection of the title “naturopath” and “naturopathic doctor”, the ability to use the prefix “Dr.”, access to a specific list of laboratory tests offered by Ontario labs and the right to incorporate a practice as a professional corporation. Achieving what we have in Ontario was due to the efforts of many people, over the last 50 years. The following chart looks at the naturopathic scope by province. Note only the provinces that have regulation, or in the case of Nova Scotia, title protection legislation, are included:

Naturopathic Authorization by Canadian Province						
	British Columbia	Alberta	Saskatchewan	Manitoba	Ontario	Nova Scotia
Date of initial regulation	1923	1948	1954	1946	1925	2008
Title protection	Yes	Yes	Yes	Yes	Yes	Yes
Doctor title	Yes	Yes	Yes	Yes	Yes	Yes
Ability to Incorporate	Yes	Yes, but not as a Professional Corporation	As a business corporation. Proclamation of new Act permits incorporation as a Professional Corporation.	Yes	As a Professional Corporation	Yes
Regulated laboratory access	No	No	No	No	Yes	No
Laboratory access outside of regulation	Yes, but not via BC lab Cos	Yes	Yes	Yes	No	Yes (no provincial lab access)
Communicating a diagnosis	Yes	Yes	Yes	Yes	Naturopathic diagnosis	Yes
Acupuncture (AC)	Yes	Yes	Yes	With AC exam	Yes	Yes
Performing a procedure below the dermis	Yes	Yes	Yes	Yes	Yes	Yes
Meso-, Prolo- therapy	With additional qualifications	Yes	With approved course	With approved course	With additional qualification. Very few substances on approved list.	Yes
Naturopathic manipulation	Yes	Yes	Yes	With manipulation board exam	Yes	Yes
Administering a substance by injection or inhalation	With Rx exam	Yes	Yes	Yes	With Rx exam and based on Tables 1-2.	Yes
Internal examinations	Yes	Yes	Yes	Yes	Yes	Yes
IVIT Therapy	With qualification	Yes	With IV course and certification	With approved course, emerg. medicine course every 3 years and CPR every 2 years.	With qualification	Yes
Prescribing, dispensing, selling and compounding substances	With Rx exam	No	No	No	With Rx exam and based on Tables 3-6.	No
Prescribing natural hormones	With Rx exam	No	No	No	With Rx exam topical estrogen, progesterone and desiccated thyroid.	No

### Substances Injected and Inhaled

#### Background

In order for NDs to have the ability to inject a substance below the dermis of the skin, a health-care practitioner in Ontario must have the controlled act of puncturing the dermis and the controlled act of administering a substance by injection or inhalation. For NDs the latter act has been amended to read “administering by injection or inhalation, a *prescribed substance*”. This means only those substances included on *Table 1: Prescribed Substances That May be Administered by Inhalation* or *Table 2: Prescribed Substances That May be Administered by Injection* within the Naturopathy Act<sup>6</sup> can be used by NDs irrespective of whether or not the substance is considered a drug, a controlled substance or over-the-counter (OTC).

The controlled act of puncturing the dermis is what allows NDs to perform acupuncture. Acupuncture has been practiced in Ontario by NDs since the 1980s, after it was added to the naturopathic curriculum of CCNM, then known as the Ontario College of Naturopathic Medicine (OCNM). In 2006 when traditional Chinese medicine was regulated under the RHPA, naturopathic doctors maintained the right to perform acupuncture as part of their scope through an exemption under the Traditional Chinese Medicine and Acupuncture Act.

#### Current Status

Under the Naturopathy Act, 2007 NDs in Ontario have the Authorized Act of, “Administering, by injection or inhalation,

a prescribed substance.<sup>6</sup> The tables below outline what NDs are currently able to administer. Table 1 outlines the prescribed substances that may be administered by inhalation and Table 2 outlines the prescribed substances that may be administered by injection.<sup>6</sup> Changes or additions to list of substances are primarily at the discretion of the College of Naturopaths of Ontario (CONO).

**Table 1: Ontario - Prescribed Substances That May Be Administered by Inhalation**

Substance	Limitations
Acetylcysteine	No limitation specified
Glutathione	No limitation specified
Ipratropium Bromide	In emergency situations
Salbutamol	In emergency situations
Saline	No limitation specified
Therapeutic Oxygen	No limitation specified

**Table 2: Ontario - Prescribed Substances That May Be Administered by Intramuscular Injection**

Substance	Comments
Diphenhydramine Hydrochloride	In emergency situations
Epinephrine Hydrochloride	In emergency situations
Ferrous Sulphate	Must be administered by z-track only
Folic Acid	No limitation specified
Glutathione	No limitation specified
Magnesium Sulfate	Must never be administered for the treatment of eclampsia or pre-eclampsia
Magnesium Chloride	Must never be administered for the treatment of eclampsia or pre-eclampsia
Saline Solution	No limitation specified
Sterile Water	Must be in combination with other substances
Viscum Album	Subcutaneous only, no limitation specified
Vitamin B12	No limitation specified
Vitamin D	No limitation specified
Vitamin K1	No limitation specified

Prior to the new naturopathic regulations of July 1, 2015, most NDs associated prescribing authority with intravenous therapy. They did not realize that they were at risk of losing the ability to provide vitamin B12 injections and glutathione, let alone meso- and prolotherapy. Vitamin B12 injections have been done by naturopathic doctors in Ontario since 1991 and inhalation glutathione has been offered to patients since 1994. With the new regulations in force NDs must now write and pass the prescribing exam in order to inject vitamin B12 or to prescribe inhalation glutathione.

Meso- and prolotherapy were introduced into the naturopathic profession in the late 1990s. Substances commonly used in meso- and prolotherapy include vitamins, minerals, plant extracts and homeopathic agents. Although performing meso- and prolotherapy falls under the controlled act of injecting a substance below

the dermis, because the substances commonly used especially homeopathics, were not included in Table 2 this meant the end (for now) of the majority of mesotherapy and prolotherapy treatments.

Thankfully, Ontario NDs still have the ability to use subcutaneous *Viscum album* which is commonly used as part of supportive cancer treatment. According to the Ottawa Integrative Cancer Centre, *Viscum album* is associated with stimulating the immune system, improving quality of life, improved cancer and treatment-related symptoms, reducing tumour size and slowing disease progression.<sup>9</sup>

### ***Impact to Naturopathic Practice***

There is no impact to practice for NDs who have passed the prescribing exam unless they were providing meso- or prolotherapy. For those who have yet to write, it means a loss of access to vitamin B12 injections and glutathione inhalation. Vitamin B12 is an essential nutrient that is associated with anemia and neurological damage when it is deficient.<sup>10</sup> There are concerns that vitamin B12 deficiency deficits may be irreversible, so early diagnosis is critical. Research shows that vitamin B12 deficiency increases with age and is more relevant in those that avoid red meat. Research also indicates that although high-dose supplementation may be as effective as oral supplementation many studies are short-term (three months or less) and there are concerns with ongoing compliance, especially in the elderly.<sup>11</sup> With an aging population and more younger individuals choosing vegetarian or vegan diets, the ability to offer vitamin B12 injections is an essential part of naturopathic practice.

Glutathione is a potent antioxidant and immune system modulator. Inhaled glutathione decreases PGE2 and increases lymphocytes.<sup>12</sup> It has been found to be effective in the treatment of asthma, chronic rhinitis, pneumonia, pulmonary fibrosis and emphysema. With an aging population, an increase in the frequency of dementia and neurological disorders, as well as chronic lung disease and asthma, the need for NDs to be able to offer vitamin B12 injections and glutathione inhalation will increase.

## **IV Substances**

### ***Background***

IV therapy has been practiced in Ontario since it was incorporated into CCNM's curriculum by Dr. Paul Saunders in 1996. The list of substances permitted at the time of proclamation in 2015 remain similar to the list under discussion with the Transitional Council following the passing of the Naturopathy Act in 2007 with the exception of four substances (alpha lipoic acid, glycyrrhizic acid, phosphatidylcholine, and silybinin and its salts) that were approved by BDDT-N around 2010, yet were not included in Table 2.

### ***Current Status***

Ontario NDs have one of the most stringent standards for prescribing IV therapy under the RHPA. *Table 2: Prescribed Substances That May Be Administered By Injection* lists the substances that have been approved for intravenous injection.

**What Comes Next**

In response to a consultation held by CONO in the fall of 2017, the following drugs and substances have been listed as “priority 1” for consideration. Some of the substances listed, such as vitamin B-complex, dextrose, magnesium sulphate and pyridoxine are already listed on Table 2. Their inclusion generally indicates that they are being considered for additional route of administration or for inclusion in tables other than those they are on already. Hopefully many of these substances will be added to the naturopathic tables, but they first have to go through a review process with CONO and then a consultation process involving the profession and other key stakeholders.

- Alpha lipoic acid
- B-complex
- Carnitine
- Dextrose
- Glycyrrhizic acid
- Hydrocortisone acetate
- Iron dextran
- Magnesium sulphate
- Methionine
- NADH 1, 4 dihydronicotinamide adenine dinucleotide
- Phosphatidylcholine
- Pyridoxine
- Silybinin and its salts
- L-tyrosine
- Vandium

Although IVIT may not be for everyone, it should be supported by all NDs. IVIT serves a very specific and essential role in naturopathic practice. Its role in adjunctive cancer therapy and addressing chronic conditions and nutritional deficiencies can be critical to positive outcomes in numerous patients.

**Drugs That May Be Prescribed, Dispensed, Compounded and Sold****Background**

Prior to the proclamation of the Naturopathy Act in July of 2015, naturopathic doctors in Ontario were unable to access natural substances that while used historically by NDs, had been placed on restricted schedules by Health Canada. These included a number of botanicals considered by Health Canada to be of high risk thereby requiring a prescription to access i.e. rawolfia, high dose niacin and high dose vitamin D.

The six tables included in the Naturopathy Act are:

Table 1: Prescribed Substances That May Be Administered by Inhalation

Table 2: Prescribed Substances That May Be Administered By Injection

Table 3: Drugs That May Be Prescribed

Table 4: Drugs That May Be Dispensed

Table 5: Drugs That May Be Compounded

Table 6: Drugs That May Be Sold

All six tables are accessible via the General Regulations under Ontario's Naturopathy Act, available at: [www.ontario.ca/laws/regulation/150168](http://www.ontario.ca/laws/regulation/150168). Last accessed 4-May, 2018.

**Current Status**

Tables 3, 4, 5 and 6 list the substances that can be prescribed, dispensed, compounded and sold, respectively, by NDs in Ontario. The lists include many of the substances listed in *Table 2: Substances That Can Be Injected*, but also include the following:

- Nutraceuticals that are considered drugs when prescribed beyond a standard dosage. Including folic acid, L-carnitine, pancreatin, pancrelipase, and vitamins A, K1, and K2.
- Natural hormones such as bioidentical estrogen, progesterone and thyroid.
- Botanicals that are not generally available OTC such as colchicine, *Digitalis purpurea* and its glycosides, podophylotoxin, *Rauwolfia* spp. and *Yohimbine pausinatalis* and its salts.

Now that naturopathic doctors in Ontario have prescribing authority, we will be in a position to acquire and maintain broader access to natural substances that are listed as drugs.

**Natural Hormones****Background**

Gaining access to natural hormones (also referred to as bioidentical hormones) and desiccated thyroid was the greatest ‘win’ for Ontario NDs. Prior to 2015, only medical doctors and nurse practitioners could prescribe natural hormones. Natural hormones are classified as drugs by Health Canada and appear on the Prescription Drug List

**Current Status**

The current regulation in Ontario allows NDs that have passed the prescribing exam to prescribe topical or suppository natural estrogen and progesterone. It also allows for the prescribing of oral desiccated (natural) thyroid. Currently, Ontario NDs cannot prescribe oral estrogen or progesterone.

NDs in Ontario and BC, despite having access to natural hormones, do not have access to testosterone and DHEA or medical cannabis. The reason is that NDs in Canada are not included as “practitioners” under the federal Controlled Drugs and Substances Act (CDSA). Currently the only practitioners that are listed under the CDSA that have access are medical doctors, dentists and nurse practitioners. The CAND has been lobbying for the inclusion of NDs under the New Practitioner Regulations for a number of years. The recent proposed regulation of cannabis has afforded the CAND another opportunity to demonstrate that NDs should be included, as they are a logical solution for patients requiring access to medical cannabis. For NDs to gain access to substances listed under the CDSA the federal government must make a regulator change and a provincial ministry of health must request that NDs in their province be granted access. This presents a significant challenge as government is always reluctant to initiate change for only two jurisdictions (i.e., BC and ON).



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### What Comes Next

The Ontario naturopathic profession has requested that CONO consider adding the following natural hormones to one or more of the naturopathic tables. After a CONO review and a subsequent consultation with the profession and key stakeholders, the root of administration and our specific access, if any, will be clarified.

- Cortisol
- Dehydroepiandrosterone (DHEA)
- Oral estrogens
- Levothyroxine (T4)
- Triiodothyronine (T3)
- Oral micronized progesterone (Prometrium)
- Testosterone

Only time will tell if any of the substances above are added to the prescribing list for Ontario NDs. Part of the decision will likely be based on how NDs in Ontario are currently practicing. According to CONO's newsletter, as of the end of 2017, only 540 NDs in Ontario had passed the voluntary Prescribing Therapeutics Exam. That represents only 38.5% of the practicing NDs in the province. By comparison, 77% of NDs in BC have written and passed the voluntary Prescribing Therapeutics Exam. CONO encourages NDs to take the Prescribing Therapeutics Exam so that they meet the Standard of Practice for Prescribing and to protect the public. As a fellow ND, I strongly encourage my peers to take the exam so that we all can continue to practice as primary care practitioners, and so that we can continue to offer our patients the range of therapies that are applicable to naturopathic practice.

## Laboratory Access

### Background

Once again, we owe a deep gratitude to Dr. Paul Saunders, ND who, in the early 1990s, worked with the two largest Ontario laboratory providers – Dynacare and LifeLabs – to create a framework that provided NDs with access to standardized blood tests. Additionally, for over forty years, naturopathic doctors in Canada have enjoyed access to non-OHIP laboratory testing including urine, saliva, stool, and breath, offered by various labs both locally and internationally. In fact, in the health-care industry, NDs are viewed as experts in the assessment of many of these tests including hair mineral analysis testing, saliva and urine hormone testing, organic acid profiles, testing for environmental toxins and heavy metals, and food sensitivity testing.

Access to standardized blood tests has truly allowed NDs to practice as primary care practitioners. However, midway through the lobbying efforts for the new Naturopathic Act it became apparent that NDs were truly at risk of losing access to ALL laboratory tests. As a result, the stakeholders had to react quickly.

Dr. Saunders and I compiled and submitted to CONO a 225-page document describing the history of laboratory access in Ontario, and justifying the need to maintain laboratory access. Thanks to

the efforts Dr. of Barb Weiss, ND the Chair of INER at the time, CCNM also sent a submission supporting laboratory access in Ontario. Many other NDs spoke up, and contributed subsequent submissions, or signed-on to the one that Dr. Saunders and I spearheaded.

At the last moment, Dr. Eric Marsden, ND, as the OAND's expert and the lead on their submission, sat in a room with representatives from the government and justified the various laboratory tests. Our victory would not have been possible without Dr. Marsden's knowledge and relentless efforts.

As a result of this collaborative effort, Ontario NDs ended up with itemized lists of laboratory tests under the Laboratory & Specimen Centre Licensing Act outlining: the 133 labs that we can requisition via blood; 7 stool tests; 28 urine tests; 15 saliva tests; 1 hair test; 7 tissue/discharge/sputum tests; 3 breath tests, and 16 specific in-house lab tests.<sup>13</sup> Overall, the lists do not reflect all we wanted, but they provide much more than was originally offered.

### Current Status

The following chart outlines what naturopathic doctors in Ontario have access to, and what we have lost access to since proclamation in 2015.

What We Have	What We Lost
<ul style="list-style-type: none"> <li>• Inclusion in the Ontario Lab Act as a health-care provider who has access to laboratory tests offered by Ontario Labs.</li> <li>• Eight detailed lists (clarifying the specimen source – blood, urine, saliva, etc), outlining a total of 210 specific laboratory tests that NDs have access to requisition.</li> <li>• Inclusion of naturopaths under the Laboratory Act. Listing NDs as one of the practitioners that can draw blood.</li> </ul>	<ul style="list-style-type: none"> <li>• Suspension of in-office blood draws. If an Ontario naturopathic doctor would like to reinstate in-house blood draws into their practice they have to apply and meet the standards of an Ontario specimen collection centre as outlined in the Laboratory regulations.</li> <li>• Access to specialized tests including genetic testing, urine testing for amino acids and many others.</li> <li>• Access to laboratory tests that are not offered by an approved Ontario Lab.</li> <li>• Access to a number a in-office laboratory tests and an inability to add new in-office laboratory tests until they are included on the lists located in the Laboratory &amp; Specimen Centre Licensing Act.</li> </ul>

Although it looks like our profession lost a lot more than it had, what we do have is significant. For example, Ontario NDs are the only NDs in Canada to have access to labs under a provincially legislated lab act. That puts us on very strong footing moving forward.

The loss of specific laboratory tests is frustrating. Even more frustrating is that other health-care professionals seemingly do not have to follow the same rules. For example, nutritionists and chiropractors, pharmacists, and even health food stores, can offer patients testing that naturopathic doctors no longer have access to. What is likely to happen is that laboratory access for all health-care

professionals will be clarified through regulation. Some professions, such as dentists, may gain access to testing (which may decrease their need to prescribe so many antibiotics!), whereas other professions, such as chiropractors will likely be restricted to laboratory testing that relates to MSK conditions.

### ***What Comes Next***

As a result of the CONO consultations in the fall of 2017, the following laboratory tests are being considered for inclusion on the lists for naturopathic doctors within the Laboratory & Specimen Centre Licensing Act:

- The only additional In-House test being considered to be added is pH Saliva;
- Blood tests: alpha-fetoprotein, anti-DNase-B, Anti-Phospholipid Antibody test, diamin oxidase, HGC, malondialdehyde, methylmalonic acid, Phospholipids A2, serum bile acids;
- The majority of urine tests being considered are those used in the assessment of environmental pollutants and toxins, such as: 8-OHdG, acrylamide metabolites, alkylphenols, atrazine matabolites, biological response to mold, cotinine, 2, 4 dichlorophenoxyacetic acid, N,N Diethyle-Meta-Toluamide (DEET), Environmental Toxicity Panel, Glyphosate and Metabolites, Metabolites of Pollutants, Mycotoxins testing, organophosphates, organophosphorus pesticide dialkyl, parabens, perchlorate, perfluorochemicals, polybrominated diphenyl ethers, polycyclic aromatic hydrocarbons, pyrethroids and urine halides, urine iodine, urine oxalate acid, urinary neurotransmitters.

Access to laboratory testing is a privilege. It is also a responsibility. Like the controlled act of communicating a diagnosis, an ND is expected and required to provide a specific level of safe and effective care. Laboratory testing is necessary to confirm a diagnosis and/or to monitor the effectiveness of treatment. A naturopathic doctor cannot do either without appropriate laboratory testing. As primary care practitioners, naturopathic doctors are expected and required to do physical exams, to ensure that they have the appropriate laboratory tests and to communicate an accurate and reasonable diagnosis to our patients. In my opinion, unless an ND is working closely with a medical doctor or nurse practitioner, it is imperative for them to utilize laboratory testing. Although lab tests requisitioned by an ND are not covered by the Ontario Health Insurance Plan (OHIP), the advantage is that access is not restricted either. Preventative health-care involves thorough and targeted laboratory testing. You will never find something that you are not looking for.

## **Regulation of Natural Health Products (NHPs)**

Health-care professions are provincially regulated in Canada, yet the regulation and classification of substances used to address health issues i.e. drugs (both prescription and non-prescription), medical devices and natural health products (NHPs) are federally regulated.

For the naturopathic profession, the CAND is on lead with the federal government. Shawn O'Reilly, the Executive Director of the CAND, has carefully and knowledgeably overseen government relations since 2002. With respect to natural health products, an interesting fact is that in the late 1990s Canadian NDs (Anthony Godfrey, Pat Wales, and Paul Saunders) were instrumental in lobbying Health Canada about the need for effective and appropriate regulation for natural health products and were instrumental in setting up the office of Natural Health Products which became the Natural Health Products Directorate (NHPD) and is now the Natural and Non-Prescription Health Products Directorate (NNHPD). The first Director General of the NHPD was naturopathic doctor Phil Waddington.<sup>4</sup> Today there are approximately eight NDs working in various directorates and departments of Health Canada including the NNHPD, Marketed Health Products Directorate and the Office of Nutrition Policy and Promotion. The CAND regularly appoints NDs to sit as experts and representatives on various working groups, advisory committees and review panels. We have a lot to be proud of as Canada has more NDs working within their Ministry of Health than any other country in the world.

Another interesting fact is that Canada, along with Australia, has some of the highest standards for NHPs. These high standards are intended to provide consumers with confidence in the products, in essence ensuring that what is on the label is in the bottle. The ongoing involvement of naturopathic doctors in the regulator process is something to be very proud of. The recommendation of NHPs is a substantial part of naturopathic treatment and hence NHP quality, safety and effectiveness have always been key priorities for the CAND. Some NDs debate as to whether or not NDs should be seeking prescribing authority. This perspective misses the fact that in Canada, some natural substances are no longer available to NDs; including some herbs and high-dose nutraceuticals, as they are classified as drugs requiring a prescription. Furthermore, anything that is inhaled or injected is considered a drug and in order to have access, or even the ability to request access in the future, NDs need to have prescribing authority.

### **NDs who have been instrumental to the regulation of NHPs in Canada:**

Pam Snider, Phil Waddington, Michael Smith, Pat Wales, Anthony Godfrey, and Paul Saunders.

The NNHPD classifies NHPs as products that are of high quality, safe, effective and available for self-selection over-the-counter. It classifies them according to schedules including what is not considered an NHP.<sup>5</sup> As NHPs are classified as OTC, no specific regulations are required for anyone to access them. Those natural substances that are on federally controlled schedules or that are administered by injection are not NHPs. The NNHPD determines the classification of every NHP based on risk. It is the lobbying by each provincial/territorial naturopathic association of their regulatory body and provincial ministry of health that determines what regulated substances, apart from NHPs, NDs can access. Following are listed the states that have regulation, and their respective prescribing access.

## Naturopathic Authorization by U.S. State

### Table Description

The table represents the controlled substances authority for Naturopathic Doctors. It indicates licensing authority granted to each category within that particular State through the Drug Enforcement Administration (DEA). If authority is granted, specific schedules are listed along with any special instructions like administer only, dispense only or order only. The Drugs and drug products that come under the Controlled Substances Act are divided into five schedules. Some examples in each schedule are outlined below.

### Schedule I substances (1)

The substances in this schedule are those that have no accepted medical use in the United States and have a high abuse potential. Some examples are heroin, marijuana, LSD, MDMA, peyote.

### Schedule II/IIIN substances (2/2N)

The substances in this schedule have a high abuse potential with severe psychic or physical dependence liability. Schedule II controlled substances consist of certain narcotic, stimulant and depressant drugs.

### Schedule III/IIIN substances (3/3N)

The substances listed in this schedule have an abuse potential less than those in Schedules I and II, and include compounds containing limited quantities of certain narcotic drugs (Schedule 3) and non-narcotic drugs (Schedule 3N) such as: codeine (Tylenol with Codeine), derivatives of babiluric acid except those listed in another schedule. Also included, anabolic steroids (testosterone).

### Schedule IV substances (4)

The substances in this schedule have an abuse potential less than those listed in Schedule III and include such drugs as: carisoprodol, barbitol, phenobarbital, chloral hydrate, clorazepate (Tranxene), alprazolam (Xanax), Quazepam (Dormalin).

### Schedule V substances (5)

The substances in this schedule have an abuse potential less than those listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotic and stimulant drugs generally for antitussive, antidiarrheal and analgesic purposes. Some examples are buprenorphine and propylhexedrine.

	SCHEDULE 2	SCHEDULE 3/3N	SCHEDULE 4	SCHEDULE 5	NOTES
Arizona	Yes	Yes	Yes	Yes	Prescribe, Dispense, Administer, Procure
California	No	Yes	Yes	Yes	Prescribe only
District of Columbia	No	3N for Testosterone	No	No	Testosterone only - Prescribe, Administer, Dispense
Montana	Yes	Yes	Yes	Yes	N/A
New Hampshire	No	Yes	Yes	No	Prescribe only
Oregon	Yes	Yes	Yes, only per formulary	Yes	Prescribe, Dispense, Administer, Procure
Utah	No	3N only	No	No	Administer & Prescribe only
Vermont	Yes. *Special Endorsement No Formulary	Yes	Yes	Yes	Prescribe, Testosterone, Codeine, Codeine combination products & Carisoprodol only
Washington	No	Yes	Yes	Yes	Prescribe, Administer, Dispense Testosterone and Codeine only

The substances NDs in Ontario can access are itemized in six tables as part of the Naturopathy Act. In British Columbia NDs have access to a broader list of drugs as rather than an inclusive list of what an ND could access theirs is an exclusionary list, setting out what they cannot access. This approach is far less cumbersome. In Ontario in order to have a substance added to the Tables the profession must lobby CONO; CONO must then consult with the profession, recommend a proposed list to the Ontario Ministry of Health, and make a case for why NDs should have access. This is a lengthy process. As part of their lobbying efforts between 2007 and 2015, naturopathic stakeholders in Ontario requested a similar process to the one used in BC, or a list by category, to no avail. This means that ongoing lobbying efforts in Ontario are required as we continually request new substances. It is important to note that it is standard practice for the RHPA to regulate all health professions in the same fashion. Although how substances are regulated in Ontario is different than BC; the regulation in Ontario is consistent with all other health-care professions under the RHPA.

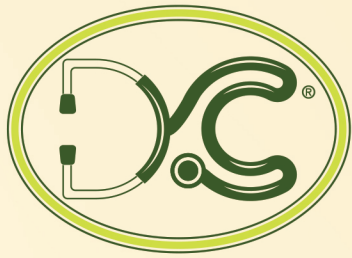
### Impact to Practice

Naturopathic doctors and the public in Canada enjoy wide access to NHPs. Since the introduction of the NNHPD, there have been a few products that have been lost (such as some glandulars and some

potentially toxic botanicals) yet overall we have maintained broad access. Over the past few years the federal government has been undergoing consultations looking at an overall set of regulations for self care products which would include cosmetics, non-prescription drugs and NHPs. It will be a risk-based approach to those products with a higher perceived risk requiring more oversight and a complete review by Health Canada (which is already in place for NHPs and OTC drugs). However, those products with the lowest risk, and making very general claims will be reviewed, but will not require a license to be sold. Instead they will be given a registration number. Plain language labelling including a 'facts table' is part of the discussion as is what products will fall into which of the three categories. This will primarily affect the labelling and statement of claims that can be made, but it could potentially affect access for a small group of products for not only the public but for NDs. The CAND is a member of the NNHPD Technical Working Group established to assist the NNHPD in the development of the new regulations. CAND has attended all consultations and continues to provide input on all discussion documents. We don't know if, or how, this will affect NDs, but the CAND is working to protect continuous access to NHPs for NDs, and the public.

Some products remain classified as NHPs up to a set dosage level.

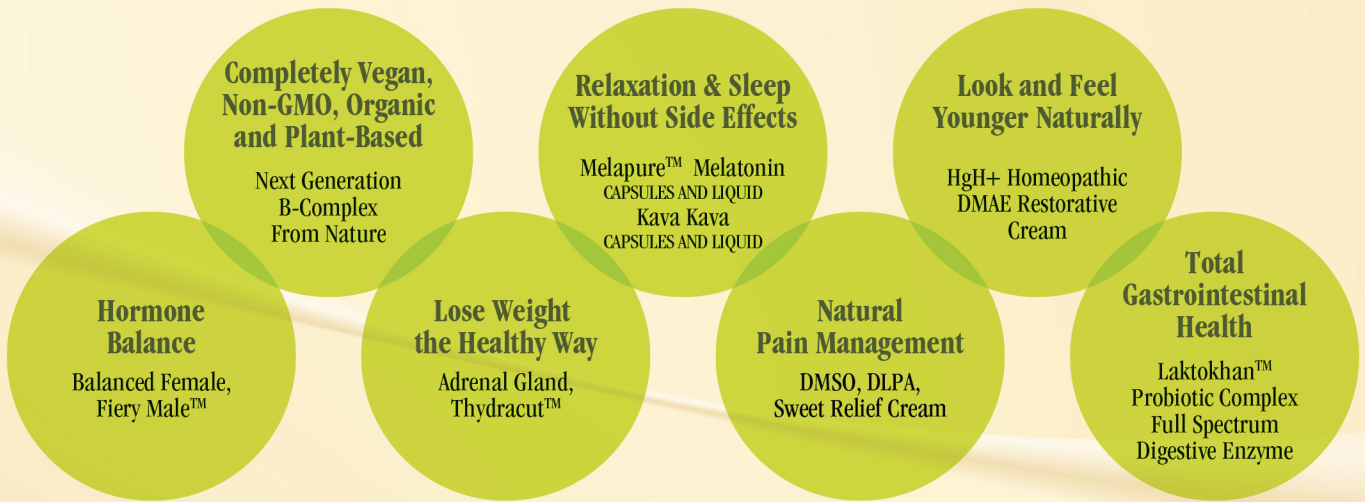




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Vitamin D is a good example. You will find that all OTC vitamin D supplements have a maximum strength of 1,000 IU. Vitamin D over that dosage level is considered a drug. Hence, if an ND needs to prescribe more than 1,000 IU a day of vitamin D, they must have prescribing authority, which in Ontario means passing the Prescribing Exam. As health-care professionals that is frustrating, but NDs need to recognize that there is a rationale.

Vitamin D is fat-soluble, and hence excess intake is not eliminated as easily. If a person takes too much vitamin D, the liver produces too much 25(OH)D, which can cause hypercalcemia. The symptoms of hypercalcemia include nausea, poor appetite or anorexia, increased thirsty, frequent urination, constipation or diarrhea, abdominal pain, muscle weakness or pain, bone pain, confusion, and fatigue. Conditions such as hyperparathyroidism, sarcoidosis and other rare diseases increase a person's risk of hypercalcemia.<sup>7</sup> Health Canada has made a number of statements cautioning the public about high-dose supplementation of vitamin D.<sup>8</sup> Despite that the literature shows there are a number of patient scenarios that benefit from high-dose Vitamin D supplementation, (reference) without passing the prescribing exam, Ontario NDs are not allowed to prescribe more than 1,000 IU of Vitamin D a day to any patient. If a patient requires 'high-dose' vitamin D, they must be referred to an ND with prescribing authority to independently assess the need.

## In Conclusion

There have been many changes in the field of medicine since naturopathic medicine was first regulated in Ontario nearly 100 years ago. Our history illustrates that a great many have done a significant amount of work to make Ontario one of the best places in the world to practice as a naturopathic doctor.

When a profession is first forming the role of education institutions is paramount. As a profession becomes established, the responsibility for guiding, protecting, promoting the profession and lobbying for access and scope falls on the professional associations. If naturopathic doctors want to remain a strong united profession, it is essential for NDs to support the national and provincial associations. The CAND is responsible for being the voice of the naturopathic profession nationally with the federal government in Ottawa. The OAND is responsible for representing the interests of Ontario NDs at Queens Park, to the naturopathic schools and to CONO. Our job as NDs is to ensure that we stay up-to-date with what is happening, that we fight for strong leadership, and that we let our voices be heard at every opportunity. There will always be change. Whether the change is good or bad depends largely on your perspective. 🍂

## About the Author

**Dr. Iva Lloyd BScH, RPP, ND** is currently president of the World Naturopathic Federation ([www.worldnaturopathicfederation.org](http://www.worldnaturopathicfederation.org)) and she is the founder and Editor-in-Chief of the website [www.ndhealthfacts.org](http://www.ndhealthfacts.org) which is designed as a hub for naturopathic information. She is part-time professor at the Canadian College of Naturopathic Medicine (CCNM) and International Liaison for the Canadian Association of Naturopathic Doctors (CAND). She has maintained a full-time naturopathic practice at Naturopathic Foundations Health Clinic ([www.naturopathicfoundations.ca](http://www.naturopathicfoundations.ca)) since 2002 in Markham, Ontario where she is the owner and Clinical Director. Her clinic has five full-time naturopathic doctors that focus on the naturopathic and energetic aspects of assessment and treatment.

Dr. Lloyd graduated from the Canadian College of Naturopathic Medicine in 2002. In addition to her ND degree, Iva has a BScH in Life Sciences from Queen's University, is a Reiki Master and a Registered Polarity Practitioner and Educator.

Dr. Lloyd has been the editor of the *Vital Link*, the professional journal of the CAND since 2005 and she sits on various other editorial boards. She has written over seventy articles for the *Vital Link*, *Energy Currents*, *International Energy*, for the *Healthy Living* magazine and for *Naturopathic Doctor's News and Review* journal, as well as other journals. She has been featured in *Chateleine*, *Glow* and other magazines.

She has done various seminars both nationally and internationally that focus on naturopathic medicine and the energetic of health. Dr. Lloyd is a consultant on preventive and naturopathic medicine, causal factors of disease and on promoting health strategies.

She is the author of four books, '*Building a Successful Naturopathic Practice*', '*Messages From The Body – a guide to the energetics of health*' and "*The Energetics of Health, a naturopathic assessment*" and "*The History of Naturopathic Medicine, a Canadian perspective*" and numerous other publications.

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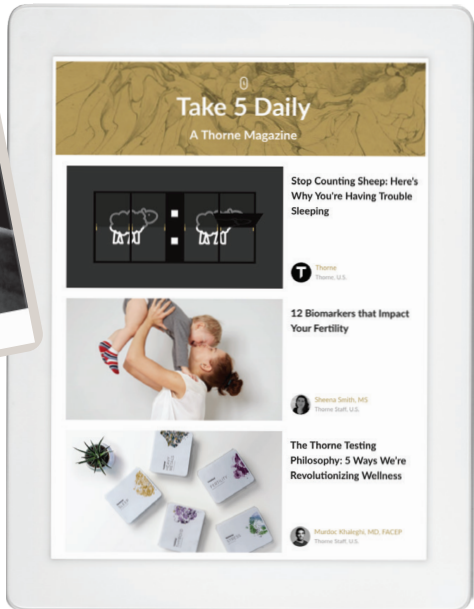
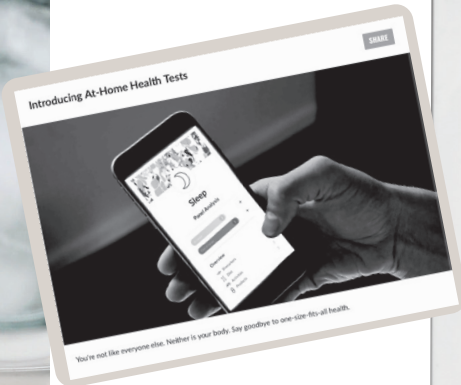
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# Natural Hormone Prescriptive Authority for Naturopathic Doctors: a Discussion

Dr. Joël Lee Villeneuve, ND

Samantha is a 30-year-old woman who when she came to our clinic was experiencing PMS symptoms, including: irregular periods, weight gain, fatigue, depression, anxiety, bloating, and migraine headaches, that were clearly related to her monthly cycle.

She had been prescribed the birth control pill (BCP) which gave her regular withdrawal bleeds every 28 days while suppressing ovulation. Shortly after beginning the BCP, Samantha began having mood swings with severe depression, more weight gain and continued migraines until she was assessed with higher levels of estrogen relative to progesterone or Estrogen dominance based on saliva hormone lab work (post discontinuing the BCP). Samantha was prescribed topical bio-identical progesterone cycled, which resolved all her symptoms completely within 12 weeks.

Mary age 49, was in late peri-menopause when she sat before me, fanning her face with a magazine. She explained the hot flashes, inability to sleep well, fatigue, lack of mental clarity, and mood changes she was experiencing were drastically interfering with her quality of life. Mary often thought she was “losing it”. She was even considering quitting the job she had excelled in for over 30 years. Once properly diagnosed and prescribed bio-identical estrogen Mary felt she had “become (her)self again”.

Tim age 52, was experiencing fatigue, a lack of motivation, low libido, weight gain and depression. Investigative blood work was performed which supported the he was diagnosis of low testosterone and high estrogen. He was subsequently treated with bio-identical testosterone by his medical doctor and a naturopathic recommendation for DIM (3,3'-diindolylmethane). Within eight weeks Tim's energy, motivation and mood increased which allowed him to obtain a promotion that only two months ago he felt was too tired to take on. His libido returned and Tim's frequent urination at night disappeared. He was thankful that his health improved without the need for the SSRI (Ciprallex) that his medical practitioner had offered.

Samantha, Mary, and Tim had all been to various medical practitioners to pinpoint the source of their health concerns. Samantha had been diagnosed by her medical doctor with being depressed and having

generalized anxiety disorder (GAD). Mary was told by her general practitioner that she was stressed, depressed, menopausal and that she needed to lose weight without offering a solution. Tim was diagnosed by his medical doctor with depression and was told that he was just getting older. Although they were all offered medications including antidepressants, they were also told that most of how they were feeling was related simply to aging and that they had to learn to live with the symptoms. Each of these patients intuitively felt something else, related to their hormones, was not right. Ultimately, as determined by a thorough naturopathic assessment, each patient's suspicion was correct.

These examples are only several of the millions of women and men who suffer from a hormone imbalance with or without a concomitant disease, influencing their overall health and quality of life. Often their concerns are misdiagnosed, or poorly treated. Women are often given BCPs for PCOS or luteal phase defects or they are prescribed antidepressants, that are not ideally targeted to help their health and which come with a host of side-effects, which limits the individual's quality of life.

As primary care practitioners, it is vital that we as naturopathic doctors (NDs) have access to laboratory testing for diagnosis and the ability to prescribe bio-identical hormones including estrogen, progesterone, and thyroid. Unfortunately, NDs in some provinces do not even have the ability to order necessary lab work. It is critical that bio-identical hormone treatment and the requisite testing should be available to everyone in need

It is also important to continue to lobby for increased access to the full array of hormones. Even in jurisdictions with prescribing authority, including Ontario, NDs are still not able to prescribe federally scheduled items (such as DHEA and testosterone). In addition, in Ontario the scope of prescribing authority for hypothyroid disease or functionally low thyroid includes only Natural Desiccated Thyroid (NDT). NDT is sourced from actual thyroid glands and contains the full spectrum of thyroid hormones including T3, the most metabolically active thyroid hormone. In the U.S., desiccated thyroid is called by its brand names, such as Armour Thyroid or Nature-Throid. In Canada, it is referred to as ‘desiccated thyroid’, ‘ERFA’, or simply ‘thyroid’. In BC, however, NDs have full prescribing authority for all forms of thyroid hormones, including liothyronine compounds.

Access to DHEA, testosterone, and all forms of thyroid is needed to be able to help our patients in practice. Were access to some of

these substances not allowed, Samantha, Mary and Tim might have become a burden on the health care system, missed work affecting the economy, and made more visits to OHIP covered practitioners. Most importantly, patients like these three might still be suffering from depression, insomnia, anxiety, and migraine headaches, which are just a few of the conditions linked to an imbalance of progesterone and estrogen.<sup>1-4</sup>

Hormones play a key role in every aspect of health. Estrogen/estradiol is vital for optimal overall mood progesterone is important for a high quality of sleep, and testosterone is well known for its positive effect on libido. A person's wellbeing requires balanced hormones for any given period. Following are some examples of the effects of hormones on human health.

## Mood

Relatively high estrogen with low progesterone levels in the body, is linked to feeling anxious and sleeping restlessly. The brain is very sensitive to progesterone which is found in brain cells at levels twenty times higher than in the blood serum.<sup>5</sup> Progesterone in the brain is derived from the steroidogenic endocrine glands or from local synthesis by neural cells.<sup>6</sup> There is evidence that progesterone can be synthesized by Schwann cells and appears to promote myelin repair in the brain.<sup>6</sup> Besides affecting the hypothalamus and other brain areas related to reproduction, ovarian steroids have widespread effects throughout the brain. These effects include the impact on: serotonin pathways, catecholaminergic neurons, and the basal forebrain cholinergic system, as well as the hippocampal formation.<sup>7</sup> Formation of new excitatory synapses is induced by estrogen and involves N-methyl-D-aspartate (NMDA) receptors, whereas downregulation of these synapses involves intracellular progesterone receptors.<sup>7</sup> Simplified, progesterone tends to have a relaxing effect, counterbalancing estrogen's excitatory effect on the brain.<sup>8</sup>

Overall, mood is also linked to a balance of neurotransmitters, especially serotonin, dopamine and norepinephrine, influenced by steroid hormones (such as testosterone, estrogen, progesterone, corticosterone, dexamethasone and deoxycorticosterone).<sup>9</sup> Low levels of estrogen can result in depressive type symptoms because it has an inhibitory effect on an enzyme monoamine oxidase (MAO). MAO deactivates the neurotransmitter norepinephrine which has a positive influence on mood. On the other hand, high levels of estrogen are also not ideal as they may be related to functional hypothyroidism.<sup>10</sup> In addition, direct effects of estrogens on thyroid cells both in the thyroid gland and in peripheral circulation have been described more recently.<sup>10</sup> Hypothyroidism causes a slowdown of cellular metabolism in both the thyroid gland and peripheral circulation, creating a drop in the calming and sleep-promoting neurotransmitters, such as gamma-aminobutyric acid (GABA).<sup>10</sup> Lower levels of GABA in the brain are associated with low mood, mood swings, panic attacks, and in severe cases epileptic seizures. In women, seizure frequency varies with the serum estradiol (E2) to progesterone ratio. The fluctuation in the ratio during the menstrual cycle is a major factor in catmenial epilepsy. Additionally, a decline in complex partial seizures and secondary generalized

motor seizures had been observed with progesterone therapy.<sup>11</sup> While GABA certainly plays a role, there is evidence that low levels of CNS progesterone may be *directly* implicated in seizure activity.<sup>11</sup> Progesterone and thyroid therapy also impact GABA levels in the brain having an anti-anxiety effect.<sup>11-15</sup>

The link of lower progesterone and estrogen levels can also be seen in mood disorders in women who experience post-partum depression (PPD), peri-menopause and or menopause. There is no consistent evidence that during the post-partum period women who develop PPD have lower reproductive hormone concentrations, have more rapid hormone withdrawal or experience greater reductions in hormone levels than women without PPD.<sup>12-14,43</sup> This has led some researchers to suggest that there is a hormone-sensitive PPD phenotype to that is triggered by the shift in reproductive hormone levels that occurs at delivery.<sup>14</sup> Even within the hormone-sensitive phenotype, influences in other biological systems including the immune system, HPA axis and lactogenic hormones are likely to contribute the pathophysiology of PPD.

Cortical GABA and the progesterone metabolite ALLO are reduced in postpartum women, regardless of the presence of PPD, compared with healthy women in the follicular phase.<sup>14</sup> Ongoing research is underway to disentangle the complex interplay of fluctuating reproductive hormones, neurosteroids, HPA axis, neural dysfunction and genetics with respect to PPD. Reproductive hormones have been shown modulate all of the other biological systems implicated in PPD: thyroid function lactogenic function the hypothalamic-pituitary-adrenal (HPA) axis, and the immune system.<sup>14</sup> Current animal studies and PPD suggest that the abrupt withdrawal of estrogen- specifically estradiol alone produces behavioral despair and anhedonia, whereas the concurrent withdrawal of progesterone and estradiol produces learned helplessness and anxiety.<sup>14</sup> Estradiol increases brain-derived neurotrophic factor (BDNF) and cAMP response-binding (CREB) protein activity which are both related to positive mood. Progesterone also regulates neurotransmitter synthesis, release, and transport.<sup>14</sup> For example, progesterone up-regulates BDNF expression in the hippocampus and cerebral cortex.<sup>15</sup> During pregnancy, the placenta produces 10-20 times the normal amount of progesterone while the ovaries' production drops to virtually zero. At delivery, the placenta's production of progesterone is removed and the ovaries over time increase their production, causing a temporary, but significant drop in progesterone, post-delivery.

In both peri-menopausal and menopausal periods reductions in progesterone and estradiol are similar to PPD through a different biochemical pathway. In peri-menopausal and menopausal women ovarian steroid production reduces from a reduced capacity of the ovaries.

Rapidly dropping estradiol and progesterone levels are strongly associated with PPD and lower mood in peri-menopausal and menopausal women. Many women with PPD, peri-menopausal or menopausal women with proper history taking, physical exam, laboratory testing to confirm the diagnosis respond well to natural estrogen and progesterone therapy.<sup>16-24</sup> Many of these patients

also need to be screened for hypothyroidism because many of the symptoms of decline in estrogen and progesterone levels also commonly present similar symptoms of thyroid dysfunction. Where indicated these same women with clinical signs including fatigue, lack of energy, hair loss, intolerance to cold, that may be suffering from unrecognized hypothyroidism benefit also from the use of 'desiccated' thyroid or pure T3/T4 custom compounded thyroid.

## Headaches and Migraine Headaches

Research shows that higher estrogen /progesterone ratios are correlated with increased headache frequency.<sup>25</sup> Bio-identical progesterone therapy can help relieve and in many cases, eliminate headaches.<sup>26,27</sup> Migraine syndromes, particularly in women, are also associated with lower levels of brain and serum ionized magnesium.<sup>28</sup> It is believed that magnesium's ability to relieve migraine distress may be related to the mineral's ability to relax vascular smooth muscle. Studies have found that as estradiol rises with low relative progesterone in luteal phase defects, ionized magnesium decreases which can be treated with supplemental progesterone which elevates ionized magnesium thereby helping to improve migraine headaches.<sup>29</sup>

## Osteoporosis

Hormone balance is key to supporting the prevention of osteoporosis. Peak bone density is approximately at age 30 for women with a rate of bone loss at about 1-1.5% per year thereafter.<sup>7</sup> As women move into peri-menopause luteal levels of progesterone decline, whereas levels of estrogen and other hormones stay the same. During this time luteinizing hormone (LH) and follicle stimulating hormone (FSH) increase. Estrogen helps to slow bone loss by curbing osteoclasts<sup>32,33</sup> while progesterone and testosterone facilitate building new bone.<sup>33</sup> Progesterone is also thought to increase insulin-like growth factor 1 (IGF-I), which promotes bone formation.<sup>34</sup> Growth hormone (GH) and IGF-I are important regulators of bone homeostasis and are central to the achievement of normal longitudinal bone growth and bone mass. Although GH may act directly on skeletal cells, most of its effects are mediated by IGF-I, which is present in the systemic circulation and is synthesized by peripheral tissues. The availability of IGF-I is regulated by IGF binding proteins. IGF-I enhances the differentiated function of the osteoblast and bone formation. Adult GH deficiency causes low bone turnover osteoporosis with high risk of vertebral and nonvertebral fractures, and the low bone mass can be partially reversed by GH replacement. GH and IGF-I secretion are decreased in aging individuals leading to an increased risk of osteoporosis.<sup>35</sup>

## Cancer

The goal of any hormone replacement therapy (synthetic or bio-identical HRT) is to restore the balance of hormones, which can improve overall health and reduce the risk of disease, including hormone dependent cancers.<sup>18,19</sup> However, most conventional practitioners are influenced by the studies presented by large pharmaceutical companies highlighting that BCPs or hormonal IUD's decrease menorrhagia, decreasing progression to hyperplasia and uterine cancer. In addition, this has also resulted in the promotion of oophorectomy/tubectomy as the standard of care for elevated risk

for ovarian cancer which is often genetically linked. What is often ignored is the increasing links of BCPs to breast cancer and heart disease, and all of the risks associated with IUDs, which themselves are substantial. The pattern of most practitioners presented with pharmaceutical-company-funded studies is to give hormones/IUDs to solve what is defined as a problem including menorrhagia, PCOS or 'regulation of the cycle' with the BCP for younger women. The focus is far from hormone balance.

It is also important to differentiate the effects of synthetic HRT from bio-identical BHRT hormone replacement therapy, however. The majority of controlled studies and observational studies in the past ten years, including the Women's Health Initiative (WHI, initiated in 1991, published in 2005, hormone therapy stopped in 2002 and unopposed estrogen stopped in 2004), suggest that the addition of synthetic progestins to synthetic estrogen in synthetic HRT increases the risk of breast cancer compared to synthetic estrogen alone.<sup>36</sup> As a consequence of the findings, which indicated that the incurred risks of hormone therapy (HT) outweigh the identified benefits, the study authors recommended that HT not be prescribed for the purpose of chronic disease prevention in postmenopausal women. In its entirety, the WHI enrolled more than 160,000 postmenopausal women aged 50-79 years (at time of study enrollment) during a period of 15 years, making it one of the largest U.S. prevention studies of its kind, with a considerable budget of \$625 million.<sup>36</sup> Due to the scale of the study, the funding granted and the publicity received, the results became the foundation to which conventional practitioners approached hormone care including the erogenous use of progestins being defined as progesterone. Because progestin (and falsely progesterone) was linked to the increased risk of breast cancer, hormone therapy for menopausal women was largely discontinued.

Other research has demonstrated that the addition of natural progesterone through BHRT/bio-identical hormone replacement therapy does not affect breast cancer risk,<sup>36,37</sup> and a large base of evidence suggests that the use of natural progesterone may act protectively and be considered as a part of combined care for the treatment of breast and endometrial cancers.<sup>38-48</sup> A study published in the *American Journal of Epidemiology* as far back as in 1981 found that women with infertility and progesterone deficiency (PD) had a 10-fold increase in deaths from all types of cancer compared to the nonhormonal (NH) cause group of infertility. In the study 1,083 women evaluated and treated for infertility from 1945-1965 were followed prospectively through April 1978 to ascertain their risk of breast cancer. Women in the PD group had a 5.4 times the risk of premenopausal breast cancer compared to the women in the NH group. This excess risk could not be explained by differences between the two groups in ages at menarche or menopause, history of oral contraceptive use, history of benign breast disease or age at first birth. The incidence of postmenopausal breast cancer did not differ significantly between the two groups.<sup>33</sup> This is an example of the studies that were available well before WHI study. However, these kinds of studies were lost in the years post-WHI, because in the public's (and much of the medical profession's) minds, progesterone and progestins are equivalent. Other related hormone imbalances including uterine fibroids, ovarian cysts,

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**NUTRIGENOMIX** 



fibrocystic breast ‘disease’, endometriosis, heavy menses and cervical may benefit from hormone balancing.<sup>49</sup>

## Male Hormone Balance

For men, the key sex hormone is testosterone, and researchers tend to place less emphasis on other sex hormones in men, including estrogen and progesterone. Progesterone is formed by the adrenal glands and testes in men in small quantities. Males that are most likely to have symptoms of excess estrogens include males who are obese or exposed to xenoestrogens (petrochemicals or plastics) in the environment. Common excess estrogen symptoms in males include gynecomastia (breast enlargement in men), reduced libido and sexual function, depression, weight gain and prostate enlargement.<sup>50-53</sup> In addition to counterbalancing the negative aspects of estrogen, progesterone supplementation may also inhibit 5-alpha-reductase, the enzyme that converts testosterone to dihydrotestosterone (DHT) which is linked to higher prostate gland health risks.<sup>54</sup>

## Estrogen Deficiency Symptoms In Women - Reduced Sympathetic Nervous System >>> Low Energy & Mood<sup>54</sup>

- Hot flashes/night sweats
- Poor sleep
- Stress
- Weight gain
- Fatigue (especially during menses)
- Low mood (especially during menses)
- Memory lapses
- Headaches (during menses)
- Hair loss
- Lack of libido
- Loss of water > deflated & dry

## Estrogen Excess Symptoms In Women<sup>54</sup>

- Decreased sex drive
- Irregular or otherwise abnormal menstrual periods
- Bloating (water retention)
- Breast swelling and tenderness
- Fibrocystic breasts
- Headaches (especially premenstrually)
- Mood swings (most often irritability and depression)
- Weight and/or fat gain (particularly around the abdomen and hips)
- Cold hands and feet (a symptom of thyroid dysfunction)
- Hair loss
- Thyroid dysfunction
- Sluggish metabolism
- Foggy thinking, memory loss
- Fatigue
- Trouble sleeping/insomnia
- PMS
- Allergies, autoimmune disorders, breast cancer, uterine cancer, infertility, ovarian cysts, increased blood clotting and acceleration of the aging process

## Progesterone Deficiency Symptoms In Women- Reduced Parasympathetic Nervous System >>> Nervous<sup>51</sup>

- Acne
- Hot flashes/night sweats
- Poor sleep
- Stress
- Uterine fibroids
- Weight gain
- Nervousness or anxiety
- Irritable (especially PMS)
- Headaches (before menses)
- Excessive nervous libido
- Water retention > swollen

Progesterone supplementation in women provides multiple health benefits including improved: blood sugar, sleep, stimulation of new bone growth and reduced anxiety.<sup>38,39</sup>

## Testosterone Deficiency Symptoms In Men<sup>54</sup>

- Erectile dysfunction, or problems developing, maintaining an erection or other changes in erections, such as fewer spontaneous erections
- Decreased libido or sexual activity
- Infertility
- Rapid hair loss
- Reduced muscle mass
- Increased body fat
- Enlarged breasts
- Sleep disturbances
- Persistent fatigue
- Brain fog
- Depression

## Conclusion

As people become more empowered to achieve their highest health potential they turn to naturopathic medicine to provide options for balancing their health and hormones. Some common concerns leading people to seek naturopathic care include: fatigue, sleep disorders, weight gain, stress and mood disorders, PMS, fertility, perimenopause/menopause, low libido, digestion, longevity, cardiovascular disease, brain health and autoimmune. Considering all of these concerns may be related to hormone balance including estrogen, progesterone, testosterone and thyroid, it is imperative that as primary care practitioners naturopathic doctors obtain a full scope of diagnostic and therapy options.<sup>7-9,16-24,26,27,32,33,51,54-64</sup>

Sir William Osler (1849-1919) the Canadian physician and one of the pioneers of modern medicine noted,

“Each patient represents a story. That story includes their diseases, their new problem, their social situation, and their beliefs. How do we understand the story? We must develop excellent communication

skills and gather the history in appropriate depth. We must perform a targeted physical examination based on the historical clues. We must order the correct diagnostic tests, and interpret them in the context of the history and physical exam. Once we collect the appropriate data, we then should construct that patient's story.<sup>65</sup>

Gathering a proper medical intake was first proposed by Osler 100 years ago. The process includes: history, physical exam, diagnostic testing as required, and prescribing appropriately. This unique approach is commonly taken by NDs, and provides patients optimum healthcare. Thus, the inclusion of bio-identical hormone therapy, and the associated laboratory testing as part of NDs' scope of practice, is vital to our ability to provide high quality primary health care.

Naturopathic doctors must continue practicing to the full scope of practice, otherwise, our ability to maintain our scope, and status as primary care practitioners could potentially be curtailed, or even reduced. A reduced scope of practice would likely weaken government regulators', and the public's, perception of NDs' overall level of competency. That could compromise our ability to provide the best care to our patients. NDs need scope expansion with hormone prescribing to practice good medicine, and we need access to labs for responsible use of hormone therapies. In addition to practicing to full scope, NDs must also ensure best practices in our service to patients; in so doing, we can provide a quality of care that is not offered by most conventional practitioners. 🍂

## About the Author

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# Naturopathic Doctors; Primary Care Practitioners Managing Thyroid Disease

Dr. Tara O'Brien, ND, and Dr. Allan Price, ND

Since proclamation of the Naturopathy Act in 2015 and the subsequent permissions to prescribe natural thyroid, or specifically desiccated thyroid, naturopathic doctors in Ontario have another tool to support patients.

It is the authors' opinion desiccated thyroid is a necessary addition to NDs' scope, as conventional guidelines for thyroid management often lead to under-diagnosis and under-treatment of hypothyroid symptoms.<sup>1-5</sup>

Many naturopathic doctors have likely wondered whether, if our patients were managed using a holistic model, would they still suffer from myriad hypothyroid symptoms?

The holistic model of patient management is one by which naturopathic doctors excel. Collectively NDs can spearhead a new paradigm for optimal diagnosis and treatment of thyroid disorders; however, this would require NDs to commit to completing the recommended prescribing courses, reviewing the complex physiology of the thyroid cascade, and including desiccated thyroid as a treatment tool. This strategy is essential to confidently diagnose and manage the many different thyroid presentations we will inevitably see in clinic.<sup>6-8</sup>

If we extrapolate from the best-documented evidence concerning prevalence in the UK and the United States, we can estimate approximately 10-20% of Canadians have thyroid disease.<sup>9</sup> This range is likely an *underestimation* of those affected as several health care provider types still subscribe to a wider range of normal (TSH range of 0.3-10 mIU/L) before diagnosing and initiating treatment.<sup>4,5</sup> It is interesting that in the most recent meta-analysis in Europe, it is estimated that about half of thyroid dysfunction remains undiagnosed.<sup>25</sup> As is the opinion of many of the authors cited herein, treatment efficacy in the conventional model requires re-assessment. For example, several of the authors' current patients who are diagnosed and taking treatment for thyroid related concerns are still very much symptomatic.

The population of Ontario is approximately 13 million. Therefore, if the national numbers are correct, that suggests that *more than* 1.3

million Ontario residents have some form of thyroid dysfunction. As of 2017 there were 1,299 naturopathic doctors actively practicing in the province of Ontario. With prescribing authority and the ability to offer prescription desiccated thyroid, a naturopathic practice is positioned to service a large number of patients – according to the abovementioned numbers, approximately 1,000 more patients per ND – who we believe would benefit from our profession's approach to diagnosing and treating thyroid disease.

We believe that holistically managing thyroid disease is a great potential opportunity for naturopathic doctors, as NDs already have the foundational training and medical knowledge aligned with the most current scientific information indicating that thyroid dysfunction is a much more complex condition than initially stated in conventional medicine.<sup>6</sup> Furthermore, as thyroid disease is postulated to affect more than 10-20% of the population,<sup>9</sup> there is a specific niche of patients waiting for the support of naturopathic doctors.<sup>13</sup> A large population of patients seeking ongoing support and care for their thyroid related health concerns could provide a financial opportunity for NDs, and have the potential to secure a patient population in naturopathic clinics finding difficulty in reaching adequate patient numbers.

## A review of thyroid function

In a healthy thyroid gland, sodium and iodine are transported into the follicular cells. In a reaction mediated by cofactors such as selenium, thyroid peroxidase, iodine is bound to the tyrosine molecules in thyroglobulin to make monoiodotyrosine (MIT) and diiodotyrosine (DIT). DIT + DIT create T<sub>4</sub> (thyroxine) and MIT + DIT create T<sub>3</sub> (triiodothyronine).<sup>14</sup>

Through protease activity, T<sub>4</sub> and T<sub>3</sub> are created and then excreted from the gland to regulate metabolic activity. Thyroxine (T<sub>4</sub>) is considered a pro-hormone while triiodothyronine (T<sub>3</sub>) is the active metabolite. T<sub>4</sub> is deiodinated in the periphery as required for metabolic activity.

The thyroid gland excretes approximately 15% T<sub>3</sub> and 85% T<sub>4</sub>.<sup>14</sup> The intelligent design of the negative feedback loop between thyroxine and the pituitary release of TSH allows a healthy body to fundamentally regulate thyroid activity once thyroid hormones are released into serum. This is the widely accepted conventional model of thyroid physiology. Recognizing this negative feedback loop is fundamental to understand the basics of the endocrine system.

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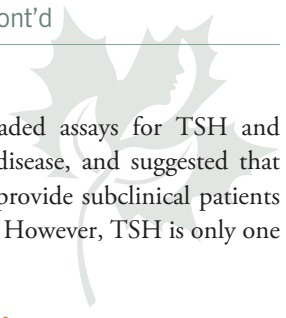
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However, applying this system to patients alone does not take into consideration the complexity of thyroid health; for example: antigenic attacks, molecular mimicry, nutritional co-factors, toxic burden, microbiome, mitochondrial defects, and so forth.

### A review of objective testing

Conventional medical practitioners tend to treat only when TSH values are overtly outside normal ranges.<sup>14</sup> The standard of “when to treat” is debated in conventional literature and reflected in the standard of practice for most primary care medical practitioners and endocrinologists.

However, naturopathic doctors recognize that patients may suffer from hypothyroid symptoms without overt thyroid disease. NDs also recognize the limitations of testing TSH only in the presence of a symptomatic patient.

The negative feedback loop between TSH and thyroxine is variable and dynamic based on a number of factors such as current T4-only therapy, age, body composition, stress levels, and nutrient status.<sup>6</sup> The current reference range for TSH (0.3 – 4.0 mIU/L) is derived from the larger population and does not take the individual metabolic variations into account.

Despite the debate about the ‘healthy range’, the TSH biomarker remains a highly sensitive and specific test for thyroid dysfunction.<sup>15</sup> Most conventional clinical guidelines recommend treatment only when TSH values are persistently above 10 mIU/L. In 2005, the National Academy of Clinical Biochemistry suggested that the normal range for TSH should adjust to 0.3-2.5 mIU/L and that all euthyroid patients receive a thyroid ultrasound to rule out autoimmunity.<sup>15</sup> The group found that 95% of the population without thyroid disease had a TSH value less than 2.5 mIU/L.

Another team also reviewed the upgraded assays for TSH and historical underestimations of thyroid disease, and suggested that the upper limit of TSH be lowered to provide subclinical patients with access to more treatment options.<sup>16</sup> However, TSH is only one part of a larger story.

### A review of a full thyroid work up

The most common symptoms of thyroid dysfunction include: persistent fatigue, anxiety, depression, hair loss, infertility, amenorrhea, weight gain, tendon and muscle weakness, digestive complaints, poor immunity, and difficulty with concentration.<sup>17</sup>

Although thyroid disease affects both genders, it predominately affects females.<sup>10,26</sup> Onset of thyroid disease may follow hormonal fluctuations in women, including initiation and discontinuation of oral contraceptives, post-partum, and post menopause.<sup>11</sup> Women are vulnerable as estrogen and progesterone activity is essential to healthy thyroid tissue and the thyroid hormone cascade.<sup>12</sup> In the authors’ clinical practice, progesterone deficiency is frequently observed, as it correlates with subclinical or overt thyroid disease.

To practice within a holistic model, naturopathic doctors should broaden a full thyroid workup to include TSH, free T3, free T4, reverse T3, thyroid peroxidase, thyrotropin, and thyroid stimulating immunoglobulin. A review of nutritional status is crucial, and involves testing levels of iodine, selenium, copper and iron as required for the overall production of thyroid hormone. A full sex and stress hormonal panel, including progesterone, estradiol, testosterone, cortisol and DHEA provides a detailed overview of the hypothalamus-pituitary-adrenal (HPA) axis. We also include a baseline vitamin D. A 2013 study published in the International Journal of Health Sciences showed vitamin D deficiency was significantly lower in hyperthyroid patients than controls and is associated with the degree and severity of disease onset and progression.<sup>29</sup>

**Thyroid Hormone Effects on Tissues**

*Table supplied by the authors*

TARGET TISSUE	EFFECT	MECHANISM
Heart	Chronotropic	Increase number and affinity of beta-adrenergic receptors.
	Inotropic	Enhance responses to circulating catecholamines. Increase proportion of alpha myosin heavy chain (with higher ATPase activity).
Adipose tissue	Catabolic	Stimulate lipolysis.
Muscle	Catabolic	Increase protein breakdown.
Bone	Developmental	Promote normal growth and skeletal development.
Nervous System	Developmental	Promote normal brain development.
Gut	Metabolic	Increase rate of carbohydrate absorption.
Lipoprotein	Metabolic	Stimulate formation of LDL receptors.
Other	Calorigenic	Stimulate oxygen consumption by metabolically active tissues (exceptions: adult brain, testes, uterus, lymph nodes, spleen, anterior pituitary). Increase metabolic rate.

A full functional work up for thyroid dysfunction will also include deep tendon reflexes, body composition, hair, skin and nail health, vital signs, lymph node assessment, and thyroid gland palpation. A detailed intake should also rule out whether the patient is at risk for unbalanced microbiome, mitochondrial dysfunction, heavy metal burden, latent viral infections and/or food sensitivities.

The benefit of the naturopathic-holistic approach is our drive to identify root cause of disease. It is possible to identify and remove causative factors to mitigate symptoms, and the need for prescription medications. The etiology of thyroid dysfunction varies from patient to patient, and could include genetic variants (alterations in sodium/iodine transport), toxicity (toxic or essential minerals), infections (Epstein Barr Virus),<sup>24</sup> nutrient depletions (e.g., vitamin D, selenium), or hormonal fluctuations.<sup>11,18</sup> There is also emerging evidence indicating the effect of the microbiome,<sup>23</sup> and the role of mitochondrial dysfunction on overall thyroid health.<sup>7</sup>

On a related note, relying on basal body temperature as a mode of diagnosing and/or monitoring treatment could limit patient management. The history of utilizing basal temperature dates back to the 1900s, after Dr. Barnes collected data from a large number of people.<sup>19</sup> Medical research has largely recommended the avoidance of this method as a primary diagnostic tool, as basal temperatures vary among healthy individuals for a variety of internal and external reasons.<sup>20</sup> With several objective measures at our disposal we can more accurately assess the need for treatment and treatment response with serum and/or urinary values, physical examinations, and robust history taking.

## The History of Desiccated Thyroid Treatment

Desiccated thyroid is manufactured from two sources: porcine and bovine; however, Canada is currently restricted to porcine sources (an issue of supply and demand, not necessarily efficacy, according to pharmacists by the authors).

Research supports natural desiccated thyroid as an appropriate treatment for subclinical and Hashimoto's thyroid disease, and has been a viable treatment option of hypothyroidism since the 1900s.<sup>21</sup> Some professional criticisms of desiccated thyroid include inconsistent T3 and T4 ratios amongst available commercial products, such as Armour Thyroid, and a lack of large scale randomized control trials.<sup>27</sup> However, Dr. Lowe, a strong advocate of T3/T4 therapy, puts forward evidence that only two recalls have ever occurred for desiccated thyroid preparations while there are several recorded recalls for manufactured T4 preparations.<sup>28</sup>

Review of the research on desiccated thyroid clearly supports the clinical use in any hypothyroid presentation,<sup>28</sup> and invariably, patients express their preference for combination therapy (T3 and T4) when compared to T4 therapy alone.<sup>30-33</sup> For example, a recent randomized, double-blinded study compared the use of desiccated thyroid to levothyroxine. Despite clinically similar objective metrics, 49% of patients preferred the natural thyroid replacement compared to 19% preferring levothyroxine due to mildly superior weight loss.<sup>21</sup>

Those patients who preferred the desiccated thyroid lost four pounds. During the course of treatment their subjective symptoms were significantly better as measured by the general health questionnaire and thyroid symptom questionnaire.

## Comparing the conventional, and naturopathic approaches to assessing thyroid health

The conventional model of thyroid dysfunction is limited and reductionist. Dosing recommendations with conventional medications are based solely on serology, despite patients' subjective complaints. Naturopathic doctors, however, are robustly trained in the factors that may disrupt normal physiology, and attuned to symptoms that may point to the complexities of thyroid dysfunction.

One of the advantages of our not being restricted by the funding limitations of a provincial health insurance model is that NDs can requisition a full thyroid work up. Medical doctors in Ontario, although having the scope of practice to order a thorough work up, are often restricted to requisitioning TSH only. As TSH is the accepted gold standard in conventional medicine, if TSH is within normal limits, there is no need for further investigation.<sup>5</sup>

By contrast, naturopathic doctors are more apt to order nutritional testing to determine deficiencies of essential cofactors for immune function and thyroid synthesis. Naturopathic doctors recognize the importance of thorough endocrine testing, which provides evidence of hormone utilization at the cellular level. NDs are also willing to explore body burden of certain substances that may be interfering with thyroid physiology.

## Considerations for a naturopathic doctor prescribing desiccated thyroid

Treatment with thyroid replacement has been clinically documented to reduce symptoms, slow disease progression, reduce the risk of nodules and goiter development, as well as shrink existing nodules and goiter.<sup>22</sup> Desiccated thyroid is one tool in the ND toolbox that can provide patients immediate relief of their hypothyroid state while underlying causes are being pursued.

The authors in their naturopathic practice introduce desiccated thyroid treatment for all patients presenting with abnormal serology and persistent symptoms, or failing to respond to T4-only therapy. The transition from T4 therapy to desiccated thyroid can be done immediately with very little risk to the patient; however, as a precaution, TSH, free T3 and free T4 values should be monitored every four to six weeks until levels are optimal and patients experience symptomatic relief. Serology is monitored every six months, and antibody activity annually to monitor dosage appropriateness and treatment outcomes.

The authors would stress the importance of regular consultations and objective testing. When applying a holistic model, dosages of desiccated thyroid are often reduced during the time causative factors



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for thyroid dysfunction are mitigated or eliminated. The ultimate goal, albeit an infrequent outcome, is that thyroid replacement therapy may become unnecessary for the patient.

Naturopathic doctors' knowledge base, and scope of practice in certain jurisdictions, such as the provinces of Ontario and British Columbia, permit us to diagnose, treat, and properly manage most presentations of thyroid dysfunction. NDs are no longer required to refer out to another health provider for prescriptions in situations warranting natural thyroid replacement. It is important to note that a prompt referral to a conventional practitioner is necessary in certain situations that are outside an ND's scope. The authors recommend a professional standard for referral if thyroid toxicosis, thyroid eye disease, or thyroid cancer is suspected. Medical referral is also necessary for thyroid ultrasound, a necessary primary care examination of thyroid nodules, as managing thyroid nodules without a definitive diagnosis may be harmful.

The benefits of taking the lead on thyroid disease presentations in clinical practice are manifold, such as the ability to better assist our patients while building a thriving practice. Unfortunately, however, the general public still has several misconceptions regarding the scope and practice of naturopathic medicine. Although the number of Canadians choosing to consult a naturopathic doctor has increased during the last decade, many may still be unaware of the level of education and the ability of naturopathic doctors to prescribe safe and effective interventions.\*

*\*Ed. note: through the market-research-supported national awareness campaign, the CAND and our regional, and academic partners are working to educate Canadians about the training, education, and capabilities of NDs as primary care providers.*

## Importance of exercising your full scope of practice

The progression of primary care in Canada relies on naturopathic doctors to challenge the reductionistic model and pursue further study to improve their expertise. Examples include: continuing to incorporate their traditional training and knowledge of nutritional supplementation to correct nutritional deficiencies, and clear body burden of toxic substances; prescribing acupuncture, botanicals and stress management techniques to counteract the detrimental effects of cortisol on thyroid function; and testing and treating latent viral infections that may be part of the etiology.<sup>21</sup> In situations where all of these factors have been addressed, and the patient still presents with symptomology or abnormal serology, the patient requires medication, which is where NDs' prescriptive authority can benefit their patients.

While NDs may be still considered 'alternative' practitioners by many of our medical colleagues, our incorporation of our full scope of practice will help reduce any bias existing among conventional medical practitioners. It is vital that the naturopathic profession is aware of the importance of demonstrating competency in prescribing;

therefore, NDs should be encouraged to complete the prescribing courses and exams, and feel comfortable prescribing. It is important to the profession that NDs utilize the right to prescribe to their full capability and competency, and necessary for NDs to demonstrate competency in their current prescription tables, adapting accordingly as our access changes, and substances are added.

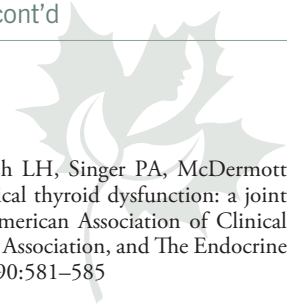
Although full competency in the management of thyroid disease is not based solely on prescribing desiccated thyroid, some patients may require a more refined dosing of T3 and T4. For the advancement of our profession and the safety of the public, NDs must continue to push for access to the full range of thyroid prescriptions as well as the ability to requisition radiological exams and thyroid ultrasound.

It is the authors' opinion that for everyone's safety, ND legislation should allow direct referral to specialists such as endocrinologists, and oncologists when managing thyroid disease. Our reasoning is that, conversely, for example, it is a backward step for a naturopathic doctor managing a patient for thyroid dysfunction to have to, upon realizing a potentially cancerous nodule exists, refer the patient back to a family physician (who historically was not managing the patient's thyroid condition) for a referral to a specialist. In such a case, the MD would have to do a complete work up prior to authorizing a referral to a specialist, which would be redundant, potentially waste time required for a good outcome, and demonstrate poor utilization of provincially funded resources. It would, therefore, seem sensible for legislation to permit NDs to directly refer to specialists.

On a personal note, the authors have been exercising their prescriptive authority since the proclamation of the Naturopathy Act in Ontario. Having the ability to support thyroid dysfunction in this way has provided our patients with many therapeutic benefits, and we believe our patients are healthier as a result.

Having the ability to prescribe improves an ND's reputation with other health professionals; for example: the authors are accepting more new patient referrals from non-prescribing health care professionals requesting investigation for thyroid dysfunction. Pharmacists have been enthusiastic to help us, and our patients; nurse practitioners and some MDs are recognizing more and more that naturopathic doctors have a necessary role in healthcare. We are of the belief that prescriptive authority not only benefits NDs' patients, but will also help to secure NDs' position in the healthcare system. 🌱





## About the Authors

**Dr. Tara O'Brien, ND** is a graduate of the Canadian College of Naturopathic Medicine (CCNM) and has an Honours Bachelor of Science degree in Kinesiology from Laurentian University. She is registered with the College of Naturopaths of Ontario (CONO) and a member of the Ontario Association of Naturopathic Doctors and the Canadian Association of Naturopathic Doctors.

In addition to her naturopathic training, Dr. Tara completed a two-year Clinical Residency at CCNM. As a resident, she assisted in teaching several courses, as well as supervising naturopathic interns at the Sherbourne Health Centre, Anishnawbe Community Health Care Centre and the Robert Schad Naturopathic Adjunctive Cancer Care Clinic. She was also actively involved in the Women's Health Program.

Dr. Tara's naturopathic practice is family-oriented with a focus on women's health, hormonal balancing, fertility treatment, weight loss, anti-aging medicine, and pediatrics. Dr. Tara practices primary care medicine using diagnostic exams and laboratory tests. She believes that an integrative approach using multiple modalities is what helps her achieve optimal results.

She has a great passion for empowering others to improve their own health, and thereby their quality of life, through naturopathic and functional medicine.

**Dr. Allan Price, ND** received his Bachelor of Life Science at McMaster University in Hamilton, Ontario, studied Nutritional Biochemistry at Laurentian University in Sudbury, Ontario and completed his post-graduate studies at the Canadian College of Naturopathic Medicine. Dr. Price has been practicing full-time since his graduation in 2000. His post-naturopathic medical studies include attending conferences, medical spas and educational courses around the world.

Highly respected by his colleagues for his efforts, studies and practice in the area of cancer support, Dr. Price has gained an interest in age prevention and enjoys helping individuals attain bioidentical hormone therapy and anti-aging medicine for skin and organ revitalization. He has also held an interest in IV nutritional therapy to support a variety of health concerns. Dr. Allan Price is a member of the Ontario Association of Naturopathic Doctors and the Canadian Association of Naturopathic Doctors.

Pure Wellness Group was opened in 2011, and along with a dedicated team, Dr. Price has aspired to provide access to naturopathic and integrative wellness for every community across Northern Ontario.

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