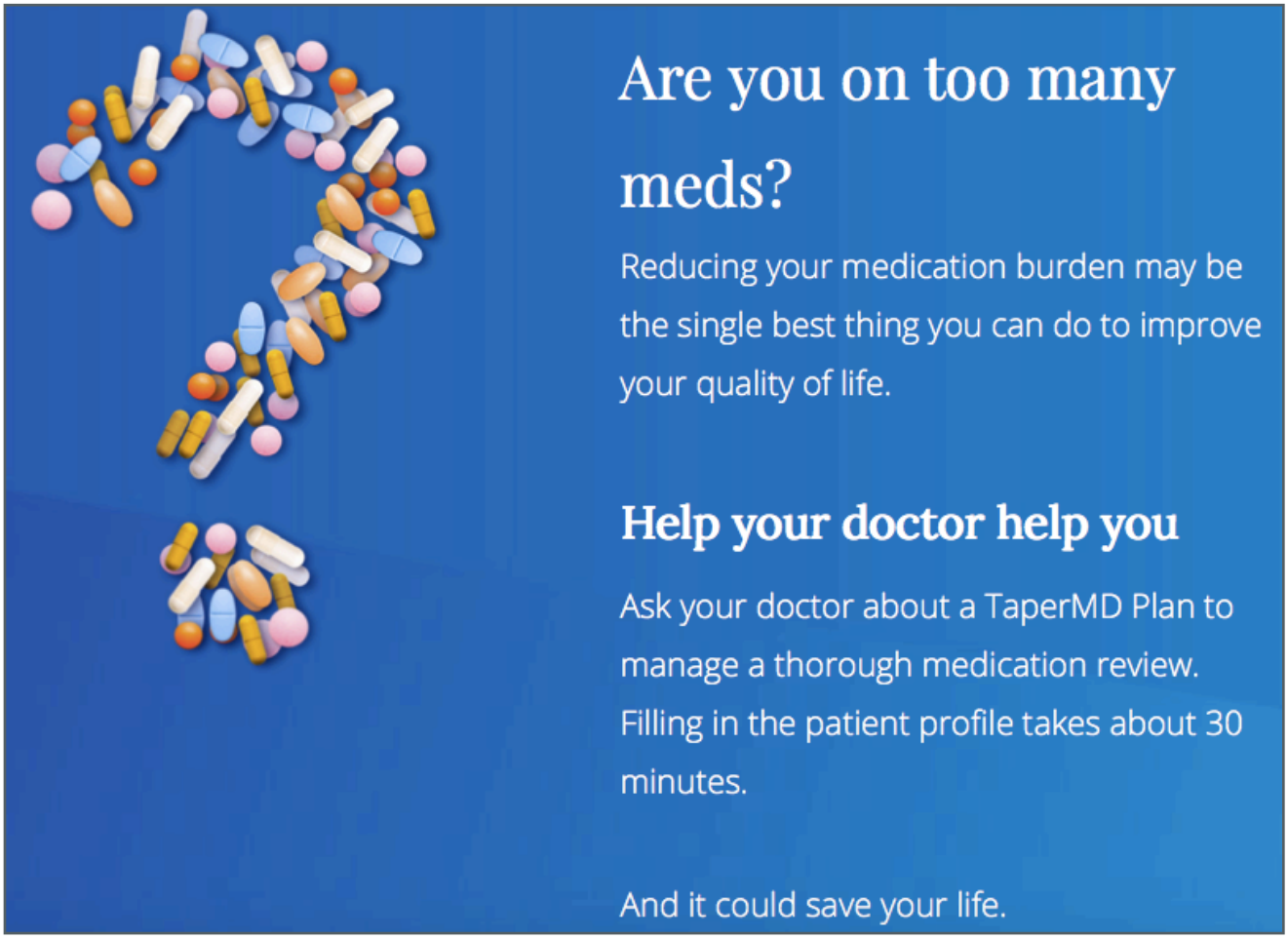
TaperMD™
Pause and Monitor



White Paper

February 2018

About TaperMD™

A MESSAGE FROM DR. DEE MANGIN

Dee Mangin

Our vision is of a medical system where explicit interventions for reducing the burden of treatment are part of routine preventive care — just like immunization and screening.

TaperMD was originally developed by Data Based Medicine Americas Ltd., in conjunction with the Department of Family Medicine at McMaster University, to help reduce the medication burden in seniors. We have used it in various research studies to validate and improve the system, and now we are offering it for broader clinical use beginning with approved beta testers.

With TaperMD, patients and their health care professionals have a simple but powerful tool to begin a meaningful conversation by discussing questions such as:

- Do I still need all of my medications or can some of them be tapered or stopped?
- Do my medications reflect my priorities for care?
- Can this effect that I am experiencing be caused by a medication?
- Can my pill regimen be simplified?
- Are there strategies that don't use drugs for my condition?

It may be that at the end of the process, patients find that they are on exactly the right medications and that no changes are necessary, but not always. Remember, less is often more!

Dee Mangin, MD
David Braley Chair in Family Medicine
McMaster University, Canada

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INTRODUCTION

Adverse drug events* are now a leading cause of hospitalization, disability, and death, all at great human and financial cost.

Adverse drug reactions have been estimated as the **fourth leading cause of death** in US hospitals and are responsible for more than 700,000 hospital visits each year. A 2006 study by the Institute of Medicine revealed that at least 400,000 preventable adverse drug events occur each year in US hospitals alone, pushing health care costs up **by about $3.5 billion annually.**

Seniors are particularly vulnerable, as aging affects our ability to process medications and our resistance to adverse effects. They are likely to be on multiple medications for various chronic conditions putting them most at risk. It is estimated that 40% of US adults aged 65 years and over take five or more prescription medications. One of the biggest health hazards for seniors is falling, often a result of multiple medications, which can cause cognitive difficulties and affect balance.

And while proper medication management is recognized as one of the most important factors for **patient quality of life,** it is clear that doctors need better support to contain the problem. In 2016, *The Washington Post* called it "'America's other drug problem:' Giving the elderly too many prescriptions."

Prescribers do not have the right tools for effectively managing patient medication plans. Their limited arsenal of ad hoc **"brown bag" medication reviews,** drug reference books, and interaction checkers are missing the mark, which is why adverse drug events continue to be such a large problem in patient care, particularly for patients over 65.

TaperMD is a revolutionary approach to medication management developed through research at McMaster University in Canada to address the serious problems of **polypharmacy and drug adverse events.**

TaperMD is a **web-based clinical decision support system** and clinical monitoring pathway that provides prescribers with tools and resources integrated with a proven methodology to manage, communicate, and review patient medication plans with a focus on **reducing the medication burden in a systematic and holistic manner.**

**Adverse drug events* refer to harm caused by appropriate or inappropriate use of a drug, whereas *adverse drug reactions* are a subset of these events — where harm is directly caused by a drug under appropriate use (i.e., at normal doses). Adverse drug events may include cases of provider error, non-adherence, or incorrect dosages.

THE PROBLEM

"AMERICA'S OTHER DRUG PROBLEM"

In a 2016 headline, *The Washington Post* called it "America's other drug problem."[1]

Older patients are being prescribed an increasing number of medications, and doctors don't have easy access to information about which medications are best for these patients or how different drugs interact.


The Washington Post
Democracy Dies in Darkness

Health & Science

'America's other drug problem': Giving the elderly too many prescriptions

Current systems of care have been designed to handle single diseases in isolation. But when following guidelines for separate issues, the treatment pieces don't always fit together anymore, particularly when it comes to medication management.

While some medications may carry a low risk of serious problems on their own, the risk of inappropriate prescriptions and medication issues increases rapidly with the number of medications taken.

We are living longer lives than ever before and receive more health care treatment than ever. But this does not automatically translate to a better quality of life.

We are living longer lives than ever before and receive more health care treatment than ever. But this does not automatically translate to a better quality of life. Proper medication management is recognized as one of the most important factors for patient quality of life.[2]

OVERMEDICATED SENIORS

A recent study found that more than one-third of seniors in Canada are on at least one inappropriate prescription — one that they don't need or that can be switched to a different drug with a better safety profile.[3] And people tend to be prescribed more medications as they age. A 2015 study found that prescription medication use among adults aged 65 years and older in the United States increased dramatically between 1988 and 2010, with the number taking five or more prescriptions tripling to nearly 40%.[4]

Risks Increase as Medications Increase

Certain medications carry a low risk of serious adverse drug reactions, but that risk increases rapidly as the number of medications taken increases.

Common adverse drug reactions include:

- Cognitive impairment, memory loss, disorientation, loss of ability to concentrate.
- Dulling of affect, mood changes, loss of interest, thought disturbance.
- Somnolence and other sleep disturbances.
- Akathisia (a state of increased tenseness, irritability, restlessness, insomnia, and a feeling of being intensely uncomfortable).
- Loss of balance and coordination, resulting in falls causing serious injury.
- Metabolic or endocrine changes.
- Skin rashes, allergic reactions.
- Anticholinergic burden, hypotension, hypertension.
- Cardiac effects, including shortened QT interval, which can lead to sudden death.
- Serotonin syndrome.

Every medication that is added to the mix increases the risk of a side effect and/or adverse interaction.

Prescribing Cascades

Many people find themselves over-medicated as the result of *prescribing cascades*.

For example, a patient on a medication presents to his or her doctor with a new symptom that is likely being caused by the medication. Instead of recognizing the problem as a medication

side effect, the doctor may add a new prescription to deal with the new symptom. If the new medication reacts badly with the original one or causes new side effects in its own right, more symptoms may appear, which get treated by more medications. This is a prescribing cascade.

Unfortunately, problems from prescribing cascades are common, especially among seniors. Once a person is taking several medications and experiencing problems, the solution is more complicated than simply reducing or eliminating some of them. Some of the prescriptions were given to address a real condition, which may be chronic. Some medications carry serious discontinuation risks, which can be more devastating than the condition for which they were originally prescribed. Every medication that is added to the mix increases the risk of a side effect and/or adverse interaction.

Non-Stop Pill Popping

"In institutionalized care, nursing homes or long-term-care facilities… it is not unusual for patients to have 20 to 25 prescriptions, their lives a non-stop ritual of pill-popping and trying to manage the side effects. While most prescribing is well-intentioned, it's also uncoordinated; there is a tendency to overmedicate and leave people on drugs for too long."[5] More than 350,000 adverse drug reactions occur in US nursing homes each year.[6]

THE COSTS ARE HIGH

Adverse drug reactions and adverse drug events are all too common, and the costs to patients and the impact on the sustainability of our health care system are high.

Many patients suffer reduced quality of life due to failure to recognize their problems as adverse drug reactions. In the US adverse drug events cause more than 700,000 hospital emergency department visits every year, with nearly 120,000 patients needing to be hospitalized for further treatment.[7]

As people age, they typically take more medicines. Adults 65 years or older are twice as likely to come to emergency departments for adverse drug events and nearly seven times more likely to be hospitalized after an emergency visit.[8] Adverse drug reactions are estimated to be the fourth leading cause of death in US hospitals — ahead of pulmonary disease, diabetes, AIDS, pneumonia, accidents, and automobile deaths.[9]

Adverse drug reactions cause more than 700,000 hospital visits each year and are the fourth leading cause of death in US hospitals.

Adverse drug reaction issues also carry significant dollar costs. One estimate placed the cost of drug-related morbidity and mortality in the US at US$177.4 billion in 2000. Hospital admissions accounted for nearly 70% (US$121.5 billion) of total costs, followed by long-term-care admissions, which accounted for 18% (US$32.8 billion). Between 1995 and 2000, the costs associated with drug-related problems more than doubled.[10]

And finally there are the costs of all of these prescribed drugs. The following table based on a 2006 study by the Institute of Medicine[11] summarizes the incidence and cost in the US of preventable adverse drug events (ADEs) in different settings.

	Hospitals	Long-Term Care	Ambulatory
Annual Preventable ADEs	400,000	800,000	530,000
Annual Cost of Preventable ADEs	$3.5 billion (2006 dollars)	—	$887 million (in 2000)

DELIVERING EFFECTIVE CARE

Most patients have never had a medication review focused on reduction of their medication burden, and once medications for chronic conditions are prescribed, they tend to just get refilled. The evidence of the harms is clear. So why are periodic medication reviews not done for every patient on multiple medications?

We have to give physicians the time and proper payment for doing detailed medication reviews.

"If appropriate prescribing is going to be the norm, then de-prescribing has to become a routine part of care. That means we need not only guidelines for prescribing, of which there are thousands, but guidelines for de-prescribing, of which there are a handful. We also have to give physicians the time (and proper payment) for doing detailed medication reviews to make sure drugs that patients are taking are appropriate and that interactions can be minimized."[12]

"Brown Bag" Reviews

The responsibility for overall management of patient medications typically defaults to prescribing doctors, with pharmacists acting as secondary screeners to catch potential issues.

Primary care doctors perform unstructured "brown bag" medication reviews — an ad hoc audit of whatever the patient has brought in. But doctors have limited time, making it difficult to capture patient priorities and spot potential problems.

Every doctor has reference materials (paper or electronic) to look up a particular drug and see what problems might occur in a patient taking it, but this is a time-consuming, difficult, and often haphazard approach, as each drug must be looked up separately. And these resources are typically little more than a list of drug interactions, rather than decision-making aids to plan de-prescriptions and substitutions.

But even a brown bag review is better than nothing. Some estimates show that fewer than half of patients with chronic conditions have had *any* kind of medication review.[13]

There are many obstacles facing health care providers in helping their patients manage their medications:

- One doctor might not know what another has prescribed.
- Patients don't perceive over-the-counter solutions and herbal products as medications and often don't think to include these on their medication lists. A recent study found that more than 42% of adults didn't tell their primary care doctors about their most commonly used complementary and alternative medicines, including a quarter of those who relied most on herbs and supplements.[14]
- Computer systems designed to flag drug interactions either don't work or are ignored as they contain a "snowstorm" of information.
- Some pharmacies emphasize fast service over patient safety according to a 2016 *Chicago Tribune* survey.[15] Pharmacies are in a unique position to catch issues, but the survey demonstrated a 52% failure rate.

In the largest and most comprehensive study of its kind, the Chicago Tribune *tested 255 pharmacies to see how often stores would dispense dangerous drug pairs without warning patients. Fifty-two percent of the pharmacies sold the medications without mentioning the potential interaction, striking evidence of an industry wide failure that places millions of consumers at risk.*

QUARTERBACKING THE MEDS PICTURE

Polypharmacy

Polypharmacy (taking multiple medications — usually five or more — routinely and concurrently) has become a serious problem in North America and around the world, and related adverse drug events are a leading cause of death, disability, and loss of quality of life. The problem continues to grow in importance because of aging populations.[16]

Blindly following guidelines from each specialty — with no one to act as "quarterback" — can practically guarantee polypharmacy

Current medical treatment tends to be single-disease-focused and therefore blind to interactions and the dangers of multiple medications. So, each of the cardiologist, endocrinologist, and rheumatologist has a point of view, but it may not reflect the broader view of the patient's conditions, treatment, and priorities. Blindly following guidelines from each specialty — with no one to act as "quarterback" — can practically guarantee polypharmacy.

Many people on multiple medications for chronic conditions have never had a comprehensive medication review, and what may have been appropriate at one point may no longer be appropriate, particularly as they age. Formal medication review plans with a focus on reducing the polypharmacy burden are close to non-existent.

Prescribers do not currently have effective tools to help them manage patient medication lists and deal with the escalating damage from polypharmacy and prescribing cascades. They need tools to:

- Assess the likelihood of a linkage between a medication and an adverse event.
- Give them effective clinical processes to develop meaningful medication plans and to implement, adjust, track, monitor, and record changes to medications.
- Capture input from patients about their preferences, lifestyle priorities, and suspected adverse drug effects.
- Manage input from other health care providers (e.g., pharmacists).
- Communicate and explain information to patients.
- Manage the discontinuation of specific medications (e.g., rate of taper, side effects to monitor for, etc.).

Although some intervention practices have been developed, there are no commercially available tools to help health care providers navigate the problem.[17] [18]

Given the high costs both to patient outcomes and to the health care system, there is clearly improvement needed in how these issues could be handled.

THE SOLUTION

PAUSE AND MONITOR

TaperMD is a revolutionary solution to the medication management gap. Developed with McMaster University, it was built to address the serious problems of polypharmacy and drug side effects, and to fit in with normal consultation processes.

- The **web-based TaperMD Portal** uses a proven methodology and provides prescribers with integrated tools to manage, communicate, and review patient medication plans. **Patients drive the process through an initial questionnaire** in which they document their medications and discuss their concerns, goals, and priorities for treatment.
- The process enables patients to better understand their medication impacts and risks, and offers them a **personalized plan** to be monitored by them and their treatment team.
- TaperMD's unique **"at a glance" presentation of each patient's medication profile,** along with cumulative drug burden information, warnings, and drill-down capability, provides prescribers with the data to make informed clinical decisions.
- The **integrated TaperMD methodology** enables prescribers to develop and manage a team-based medication plan with a focus on reducing patient medication burden in a systematic and holistic manner.
- TaperMD's **Snapshot view** provides a mobile-friendly overview for each patient medication plan, which can be exported into an electronic medical record or shared with the patient.

The Right Information, at the Right Time, in the Right Place

We've designed TaperMD to support a systematic primary care pathway to reduce the medication burden on older adults. Health care providers create their own TaperMD Portal and can add patients and caregivers to the Portal.

Through a team approach, a TaperMD Plan is created and monitored.

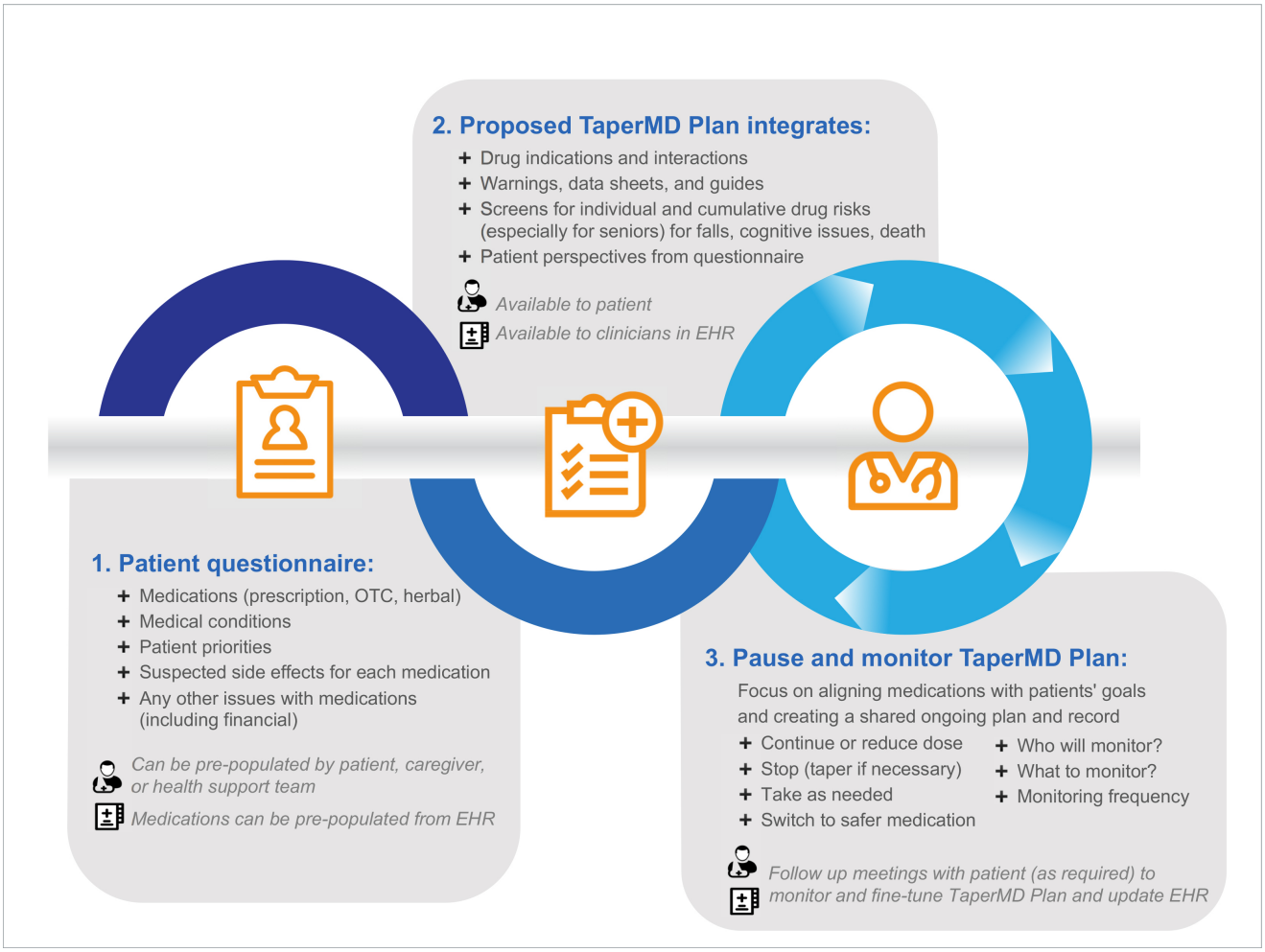
The TaperMD solution helps health care providers manage, communicate, and review medications for their patients.

TAPERMD METHODOLOGY

The TaperMD tool is designed to allow coordination of care across providers and help:

- Understand and capture patient priorities and preferences.
- Assess the linkage between a medication and an adverse drug event.
- Manage prescribing of and reducing or stopping specific medications.
- Structure clinical processes to develop, implement, and monitor medication plans.
- Collaborate with input from multiple health care providers.

It is important to include patients and their advocates in the process, as they have the biggest stake in improved patient outcomes. Educated patients are more likely to request proper medication reviews from their prescribers if they are aware of the benefits.



WHO WILL BENEFIT?

The initial *beneficiaries* of the TaperMD service are people taking five or more prescription drugs for chronic conditions. However, prescribers and others making health care decisions for these older adults are essentially the *customers* of the service, even though they are not the people taking the medications being monitored and managed.

The TaperMD service will be of interest to:

PATIENTS

The benefits to patients are better quality of life, and longer and healthier lives. They may also benefit from lower costs for medications where alternate cheaper medications are substituted (but that are just as effective and with fewer side effects). Patients will also have direct input into documenting their medication profile and priorities, as well as a record of their TaperPlan, and will be able to better understand what they and their doctor have agreed on and next steps.

HEALTH CARE PROVIDERS

Physicians will benefit from using TaperMD to provide better care within the time constraints they face. They will have accurate and complete information by having patients pre-populate their medication profile and priorities, as well as instant access to reference materials, screens for potential dangers, and a proven methodology to document and monitor a Taper Plan.

INSTITUTIONS

Institutions such as hospitals and long-term care facilities will benefit from a reduction in the number of adverse drug events such as falls, and the related benefits of better outcomes, lower costs, and healthier and more satisfied users and families.

PAYERS

Payers (whether government, insurance companies, or corporations) will benefit when the significant burden of adverse drug reactions is reduced. Measurable results will include:

- Reduced number of adverse drug reactions, especially expensive ones that require hospitalization.
- Lower readmission rates for inpatient care for those suffering an adverse drug event.
- Reduced number of medications used per patient and related savings.
- Increased patient satisfaction and reported improvement in quality of life.

LEARN MORE ABOUT TAPERMD

TaperMD is in Beta and is in clinical trials in Canada and Australia.

We are currently accepting applications for Beta testers at a reduced subscription price. This represents an ideal opportunity to implement TaperMD in your practice and provide your feedback on any features and benefits you would like to see added.

To learn more about becoming a TaperMD Beta tester visit: tapermd.com/beta-test.

We will be starting off with Beta testers in North America, but will gladly accept applications from other countries for future rollouts.

If you are a patient who is concerned about your medication burden, let your doctor know about TaperMD and the white paper, which can be downloaded at TaperMD.com/learn-more.

ABOUT DATA BASED MEDICINE AMERICAS LTD.

TaperMD is a line of business in Data Based Medicine Americas Ltd., a Canadian Corporation with a legal and tax footprint in Ontario. Both Dr. David Healy and Dr. Dee Mangin of our medical team have global reputations as thought leaders and experts in adverse drug effects, the underlying systemic problems contributing to adverse drug effects, and patient-centred care.

We also operate a free public website, RxISK.org, to allow medication research and to provide an individualized RxISK Report and RxISK score to inform discussions between the patient and the patient's provider on the possible linkage between the suspect medication and an adverse event.

DR. DEE MANGIN

Dr. Derelie (Dee) Mangin, our Chief Medical Officer, is a family doctor originally from New Zealand, where she was director of the Primary Care Research Unit at Otago University in Christchurch.

Dee was an advisor to the New Zealand government on drug treatment funding priorities and served on the Southern Region Ethics Committee. She is a Fellow of the Royal New Zealand College of General Practitioners and in 2011 received their Distinguished Service Medal.

Dee moved to Canada in 2013 to become the David Braley Nancy Gordon Chair in Family Medicine and Research Director at McMaster University in Ontario, Canada. Her research is focussed on multi-morbidity, polypharmacy, and matching medical care to patients' priorities and preferences.

An advocate for better independent information for patients and their doctors on drugs, Dee sits on the Section of Researchers' Council with the College of Family Physicians of Canada (CFPC) and is a member of the Canadian Patient Safety Institute.

DR. DAVID HEALY

Dr. David Healy, CEO and principal founder of Data Based Medicine Americas Ltd., is an internationally respected psychiatrist, psychopharmacologist, scientist, and author.

A professor of Psychiatry at Cardiff University in Wales, David is a former Secretary of the British Association for Psychopharmacology, and has authored more than 200 peer-reviewed articles and 20 books.

David has been involved as an expert witness in homicide and suicide trials involving psychotropic drugs, and in bringing problems with these drugs to the attention of American and British regulators. His book *Pharmageddon* documents how the data from clinical trials has been sequestered and how most of the academic literature on treatment effects is now ghostwritten with life-threatening results.

ENDNOTES

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