Non-Prescription Medication Compliance: Focus Groups with Non-compliant Consumers

A Research Report to the Non-prescription Drug Manufacturers Association of Canada (NDMAC)

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1. Strategic Summary

The non-compliance seen among users of non-prescription medication in this research was generally far from extreme or reckless. As noted later in this report, most non-compliance manifested as taking up to twice the recommended dose at one time *or* taking an additional dose before the end of the recommended interval period. Among the 63 participants in the focus groups, almost all were engaged in *episodic* non-compliance - once every few weeks or months - rather than *chronic* non-compliance. This is not to minimize the significance of their behaviour, but it is critical to understanding how they comfortably rationalize their decision to occasionally diverge from package directions. Regardless of their own non-compliant behaviour, they remain ready to question and criticize non-compliant use of others which goes beyond their own. They are especially critical of *chronic* overuse of medications or single doses which range beyond two to three times the recommended amount.

Like most human behaviour, compliance with directions for non-prescription drugs rests on an analysis of perceived costs and benefits. As this report shows, however, this analysis is lopsided when it comes to non-prescription medications. Users must weigh very clear benefits (in the form of perceived gains in pain relief and symptom relief) against largely unknown costs which are rarely if ever evident in their own lives. They must balance their own *experience* of benefits from non-compliance against *assertions* by others that non-compliance is unwise. And often they must do this at moments when they are in significant physical discomfort. Not surprisingly, many choose to obey their own experience rather than injunctions or limitations found in the medication directions.

Non-compliant use is rarely based on poor knowledge of directions or sheer recklessness regarding the health consequences. Instead, it is a “rational” choice based on personal experience and in the absence of certainty about negative consequences. Non-compliant users believe that, for them, their behaviour is appropriate and reasonable even if it varies from the package directions. Non-compliant use is not something that occurs the first time they use a medication, but a pattern of behaviour which evolves over time as they become more familiar with the effects they can expect from a particular medication. Consumers say they are driven to non-compliance primarily by suffering. It may be that for many, a single desperate incident compels them to cross the line into non-compliance and, upon discovering there are no obvious consequences, they then become habitually non-compliant. Canadians who *always* comply with instructions may do so, in part, because they have never felt forced by suffering to cross that line.

Their reasons for diverging from directions are varied, but consumers verify the “safety” of this behaviour in their own lives through trial and error. They generally assume that they will feel some *physical* sign – nausea, dizziness, somnolence - that their use of the medication has moved beyond what is reasonable *for them*. Non-compliant users are somewhat aware that long term or asymptomatic damage could occur from non-compliance, but generally assume

this would result from much larger doses than they take themselves and, more critically, that such outcomes require chronic non-compliance over the course of weeks and months.

As it is borne of personal experience, most non-compliant use is closely tied to a specific product or brand. It is not uncommon for non-compliant users to condemn as unwise any form of non-compliance *except* that which they pursue with their own preferred product or brand. A person might believe that the directions should always be followed for example, but make an exception for their own brand of pain reliever in their own particular circumstances. While they might exceed the recommended dose on that pain reliever, they would not exceed the recommended dose on *another* pain reliever or another class of non-prescription medications. Their non-compliance is not a matter of overall attitude toward compliance but instead a specific behaviour tied to a specific product with which they have experience. As noted earlier, this experience is that they obtain relief of their symptoms – relief which they believe to be better because they exceed directions – and suffer no ill-effects as a result.

Given that non-compliance is based on personal experience and the fact that the perceived benefits outweigh the perceived risks, non-compliance is clearly a difficult behaviour to change. The unavoidable conclusion – frequently echoed by users themselves – is that these consumers require a clearer understanding of *why* the directions for use should be followed. They need, in short, a far greater sense of potential *consequence* than they have now and specifically a greater sense of negative health consequences which may not be physically apparent to them a the time. An important adjunct to providing this information would be to provide the information through a variety of channels with high levels of credibility. Package directions and warnings – even if more explicit and accessible than today – should be reinforced with messages from industry, government, physicians and pharmacists.

In sum, it is clear from this research that non-compliance is generally limited and based upon a rationale, rather than upon misinformation or disregard for consequences. As a result of these discussions with non-compliant consumers, the nature and extent of the problem is clearer, and a number of potential concerns have been eliminated.

2. Executive Summary

2.1. Sources of Information

- Almost all respondents claim to read the instructions on the non-prescription medications they buy. For most, this is a one time effort, after which they are satisfied they know how to use the product.
- Respondents believe Directions for Use are based primarily on scientific principles (rather than mercantile interest.) They are considered to be conservative, however.
- In contrast to the Directions for Use, relatively few respondents - less than one half - *ever* read the 'insert' provided with some medications
- Although widely used, package directions are not always considered trustworthy – they are considered to be conservative for reasons of liability.
- Both the Directions for Use and the Package Insert were repeatedly criticized for illegibility. The print was considered too small, too cramped, and insufficiently direct.
- Pharmacists, physicians and package directions are currently the three key sources of information for consumers about the use of non-prescription medications.
- Pharmacists enjoy a higher reputation for expertise (and accessibility) than physicians, although the directions of a physician often still appear to hold more authority over actual behaviour.
- Web-based sources have been used by perhaps one-third of respondents seeking to learn more about a particular medication.

2.2. Concern About Non-compliance

- Respondents consider themselves *reasonable* and *responsible* users of non-prescription medication, despite their own non-compliance. This confidence stems from experience with their preferred products and a knowledge of their own bodies.
- The only cause for concern, in their eyes, is extreme non-compliance, chronic non-compliance, and possible interactions with alcohol or prescription medication.
- Many assume that non-prescription medications are inherently less dangerous than prescription medications and that only significant misuse of them could cause harm.

2.3. Types of Non-compliance

- There are four types of non-compliance demonstrated by the respondents in this study:
    - Excess single dose at one time.
    - Using medications for purposes not indicated ("Off label" use).
    - Inadequate time interval after taking maximum dose before taking more.
    - Exceeding the daily maximum dose.

- Of these four types of non-compliant use, the most common *by far* is the use of an excess single dose ranging from 1.5 to 3 times the recommended amount.
- Perhaps one respondent in ten acknowledged that they have used ND medications for purposes other than intended. Their objective, always, was to induce sleep.
- It is quite rare for respondents to report breaking the interval or exceeding the daily dose.
- One type of possible non-compliance which was not evident in the groups – although probed – was the mixing of incompatible medications.
- In this study, five specific reasons for non-compliance emerged. Most of these relate to suffering and the need for relief:
    - Extreme suffering
    - Faster relief
    - Fear of returning symptoms
    - Body Weight
    - Assuring Performance
    - Bringing on sleep
- Of these reasons for non-compliance, extreme suffering was by far the most commonly-cited reason to exceed package directions.

2.4. Negative Consequences of Compliance

- Almost all respondents acknowledge that non-compliance may entail negative health consequences. Yet, there are very wide variations in the types and severity of those expected consequences. There is also considerable diversity (and uncertainty) regarding the amount of medication which would cause negative consequences.
- Most respondents assume that the Directions for Use printed on non-prescription medications include significant margins of safety. In other words, they believe that most people could safely take more medication than recommended on the package without ill effects.
- There is a great deal of uncertainty about how large these margins of safety actually *are*, however.
- Respondents believe that between 6 and 8 regular Tylenol/Acetaminophen (325mg), taken at one time, would begin to be harmful to the health. They believe between 4 and 9 Advil/Ibuprofen (200mg) in a single dose would be required to damage the health. In both cases, the 'damaging dose' is thought to be between three and four times the recommended dose.
- Remarkably, there is a widespread assumption that users would *know* if they had taken too much of a specific non-prescription medication.
- Respondents identify a number of reasons why exceeding directions on non-prescription medications might be unwise. The most common by far are: addiction,

developing a tolerance, masking a serious problem, or liver damage. Note that only one of these is a classic “adverse medical effect.”

- Respondents do not distinguish clearly between the normal side effects of a medication, adverse affects such as allergy which might be experienced at any dose, and the specific symptoms caused by exceeding manufacturer’s directions.

2.5. Changing Compliance Behaviour

- While consumers are sometimes concerned about the non-compliant use of others, they are rarely concerned about their *own* divergence from directions. As discussed earlier, they view their own behaviour as reasonable and responsible, based upon experience and self-knowledge.
- Thus, they are not particularly seized with the question of how government or industry might convince them to change their non-compliant behaviour .They do offer five specific suggestions, however:
    - Specifically explain the potential consequences of non-compliance
    - Improve the format of warnings on packages
    - Undertake public awareness advertising
    - Use pharmacists and pharmacies to provide information to consumers
    - Provide dosage instructions by body weight
- Of these suggestions, the strongest emphasis is upon the explanation of consequences.

3. Introduction

Redfern Research is pleased to present this report on the use of non-prescription medications by Canadians. In July 2007, the Non-prescription Drug Manufacturers Association of Canada (NDMAC) commissioned Redfern Research to conduct a research study of Canadians, centered on 14 focus groups with consumers who deviate from package directions when using non-prescription medications

4. Objectives

To further the existing understanding of non-prescription medication use among Canadians, this study had four primary objectives.

- To understand the information sources consumers use to learn about the importance (or otherwise) of compliance.
- To understand the nature of non-compliance.
- To identify root motivations underlying non-compliance, including non-compliance based on misinformation, experience, or on advice from health professionals.
- To identify perceived negative consequences of non-compliance.

5. Research Approach

This research project encompassed 14 focus groups with Canadians who acknowledge having exceeded dosing instructions on a non-prescription medicine during the previous month.

Respondents were chosen from the general population, according to the following criteria:

- They must be aged 18 to 65; and
- They must answer **yes** to the following question: “Non-prescription medications usually specify how much to take and how often. At any time during the last six months have you ever taken more of a medication than is recommended or taken it more often than recommended? For example, you might have taken more pain killer tablets at one time than suggested on the box, or taken a cold medication more often in a day than is recommended.

Focus group participants were recruited by telephone to one of six groups in either Toronto or Montréal. The focus group schedule is shown below. Participants received $75 for their participation.

Group Number	Location	Participants*	Language	Date
1	Toronto	Men (46 to 64)	English	Wednesday, July 25
2	Toronto	Men (26 to 45)	English	Wednesday, July 25
3	Toronto	Men (18 to 25)	English	Wednesday, July 25
5	Montreal	Women (46 to 64)	French	Monday, July 30
6	Montreal	Women (26 to 45)	French	Monday, July 30
7	Montreal	Women (18 to 25)	French	Monday, July 30
8	Montreal	Men (46 to 64)	French	Wednesday, August 1
9	Montreal	Men (26 to 45)	French	Wednesday, August 1
10	Montreal	Men (18 to 25)	French	Wednesday, August 1
12	Toronto	Women (46 to 64)	English	Wednesday, August 8
13	Toronto	Women (26 to 45)	English	Wednesday, August 8
14	Toronto	Women (18 to 25)	English	Wednesday, August 8

The focus groups were split by gender and age. This was not done primarily because major differences were expected between these groups, but in order to encourage conversation. Typically groups containing only men or women are more productive, as are groups which contain only younger or older people. Groups divided this way usually develop more group cohesion and tend to ‘speak the same language’, thereby improving the overall quality of the discussion.

Focus group in Montréal were recruited by Ad Hoc Research and moderated in French by Joanne Egglefield. Focus groups in Toronto were recruited by Opinion Search and moderated in English by Martin Redfern. All aspects of the research were coordinated by Redfern Research.

The groups were conducted in accordance with a Discussion Guide, designed by Redfern Research, a copy of which is appended to this report.

5.1. Talking to Canadians About Compliance

This research brought non-compliant users of non-prescription medications together to discuss the subject of these medications and how they should be used. It is important to describe at the outset the degree of familiarity and understanding these respondents have on this subject.

The participants in these groups had little or no trouble distinguishing between prescription medications, non-prescription medications, and supplements such as vitamins. The discussions were solely about non-prescription medications and the participants were disciplined in treating this product segment in isolation. There is no reason to believe their comments regarding compliance related to other product types, whether Rx or supplements. (The groups started with a roundtable listing of ND products used, and these lists were almost uniformly populated with only ND medications.)

Although some reported using skin preparations, fungal treatments and eye and nose drops, most of the conversation necessarily revolved around pain medications, cold and allergy

medications and, to much lesser extent, stomach remedies. This is because these are the products which most participants use. This was also advantageous, because these products have clear dosage directions and compliance is easy to assess. Unfortunately, the time of year meant that use of cold medications were less recent and less discussed.

Health and medication is a personal and individual thing, and our participants can only speak from their own experience and those of people in their immediate surroundings. Before coming to the focus groups most had clearly never given much thought to overall questions about compliance, instructions and potential consequences.

While the conversation was about non-prescription medications in general, respondents have experience specific products not the entire class of products. Thus, their knowledge and opinions tended to be limited to their own preferred products. Discussions about the category as a whole were often vague and uncertain, while discussions about specific products were often much more substantive and meaningful.

There is only limited understanding of the active ingredients contained in non-prescription medications, especially outside the pain reliever category. This means that respondents do not generally think *clearly* about extra strength formulations versus regular strength formulations. Relatively few participants were able to speak in terms of milligram dosages or compare different medications. Thus, comparative discussions with consumers tend not to be overly sophisticated. This reinforces the importance of expert opinion and the Directions for Use, because most consumers cannot generalize their experience and knowledge of one medication to others.

A small but important point, noted later, is the fact that respondents cannot distinguish between side effects, adverse drug reactions and symptoms of overdose. They generally expect non-prescription medications to have no side effects at all, and view any side effects – even those known effects associated with a regular dose – to be unusual and cause for concern.

Finally, as noted later, almost all consumers say they read the directions for use on non-prescription medications, at least when they first buy a particular product. This meant that participants were able engage meaningfully on discussions about their own compliance and non-compliance, speak within a realistic window of behaviour, and think clearly about the format and content of package directions. These discussions were highly focused and informed.

5.2. Potential Weaknesses in the Data

There are two potential weaknesses in these results, each of which are somewhat inherent in the subject at hand.

First, we rely upon non-compliant consumers to self-identify for these focus groups. In other words, we only recruit people who know and report that they have not complied with package

directions at least once in the last six months. By definition this excludes people who are unaware that they have been non-compliant. This is a known limitation of the research design, the only alternative to which would be to verify the medication use of potential participants against a catalog of medication directions. Other NDMAC research has identified that unwitting compliance is relatively rare and that most non-compliance is conscious and deliberate.

Second, we rely upon consumers to be honest about their use of medications. This means that some people who misuse non-prescription medications may nonetheless exclude themselves due to embarrassment or fear of repercussions. There is no reasonable way to remedy this weakness in a focus group project. This report acknowledges that rare cases of extreme or recreational non-compliance are beyond the scope of this inquiry, and focuses instead upon 'mainstream' non-compliance.

5.3. A Note on Qualitative Research

Qualitative research is not intended to provide a statistically-reliable reading on the wider population from which participants are drawn. Instead, focus groups provide insight into the way people think about and react to ideas and concepts, their understanding of the subject, and their behaviour and motivations. Although extremely useful, this focus group research cannot be generalized to the wider population with any known degree of statistical accuracy. The key themes identified in this report are very likely present in the wider population, but we cannot estimate in what proportion they are present with any known degree of statistical reliability.

6. Detailed Findings

6.1. Information Sources on the Use of Non-prescription Medications

6.1.1. Directions for Use

Almost all respondents claim to read the instructions on the non-prescription medications they buy. For many, this is a one time effort, after which they are satisfied they know how to use the product. They will buy additional packages of the product without again reading the instructions for use. The only instances where respondents say they recheck the instructions on products they use regularly is to verify the interval time between doses. This is usually because they want or need to take more medication as soon as possible to combat symptoms.

New medications (including different brands of the same medication) are treated differently from the brands respondents buy regularly insofar as they will read these instructions carefully before use.

While they may diverge from the directions for use, respondents believe these instructions are set primarily by scientific principles (rather than mercantile interest.) Most assume the instructions are designed by medical staff and researchers employed by the manufacturer, with some unknown degree of oversight by 'government'. Others have no real sense of where these instructions come from. Nonetheless, almost all respondents believe the directions for use are science-based.

In contrast to the Directions for Use, relatively few respondents - less than one half - ever read the 'insert' provided with some medications which provides more detail on contraindications and side effects.

Both the Directions for Use and the Package Insert were repeatedly criticized for illegibility. The print was considered too small, too cramped, and insufficiently direct. As is often the case, this criticism was most common among older respondents who joked that the package 'should come with a magnifying glass.' It is impossible to know whether print size is a significant barrier or simply an excuse masking disinterest. It seems fair to assume that consumers would read this information if they sincerely anticipated any health risk from their medications. As noted later, that sense of risk is relatively weak when it comes to consumer perceptions of non-prescription medications.

6.1.2. The Role of Other Information Sources

Without doubt, package directions are the primary source of consumers use for instructions on how to use non-prescription medications. If they seek information from any other source, it is a pharmacist or a physician. Perhaps one-third of respondents have spoken to a pharmacist

about a non-prescription medication. About half of this advice relates to finding the most appropriate (or least expensive) medication for a particular problem. Other conversations are often related to possible interactions between NDs and prescription medication or to appropriate medications and dosages for children.

In open discussions, respondents say pharmacists enjoy a higher reputation for expertise (and accessibility) than physicians, although the directions of a physician often still appear to hold more authority over actual behaviour.

Web-based sources have been used by perhaps one-third of respondents seeking to learn more about a particular medication. Some visit manufacturer websites, but many appear to use search engines, acknowledging that not all web sources are equally reliable. Once again, they are often looking for information on potential interactions with other medications.

Most respondents do not explicitly mention the influence of friends and family, but this may be somewhat misleading. It is very clear that attitudes toward non-prescription medications (including Directions for Use) evolve through childhood in response to family practices. Most adhere to their parents' approach, while a few react against it. Nonetheless, it is clear that most people receive advice from family and friends, and many take this advice seriously. At the very least, other family members serve as an example against which people compare themselves. ("My husband is a real pill popper.", "My Mom never takes pills and gets mad when I do.")

A final source of information, mentioned only in Québec, are government health service lines. Info-Santé was mentioned by perhaps one-fifth of respondents in Quebec. In Ontario, Tele-Health source was never mentioned spontaneously.

6.1.3. Current and Trusted Sources of Information

Given a list of potential information sources in questionnaire format[1], respondents generally confirm their comments in the earlier "unprompted" conversation. As the following figure shows, there are few "major" sources of information beyond package directions, physicians and pharmacists.

There are some interesting differences, however, between the information sources which consumers mention unprompted as compared to their response to this list. First, physicians were clearly secondary sources compared to pharmacists and package directions during open discussion. Physicians were in fact criticized for a lack of availability and sometimes inferior knowledge of drug interactions. As noted earlier, physicians appear to hold considerable *authority* in general, however, and participants are inclined say they are the most important

[1] The numerical nature of these results should not be misconstrued to suggest that they statistically represent the population. Instead, these figures are intended to provide a summary of the focus group

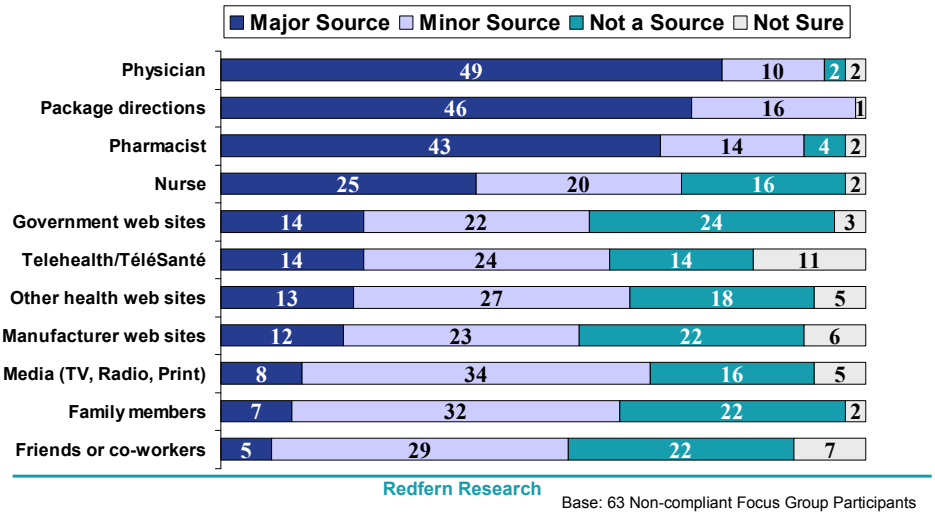
source of information. This does not alter the fact that pharmacists were mentioned much more often during unprompted discussions about information sources.

Similarly, Tele-Health was never mentioned as an information source during the groups in Toronto, and yet more than one-half of participants indicate is currently a source of information.

These differences notwithstanding, it remains clear that pharmacists, physicians and package directions are currently the three key sources of information for consumers about the use of non-prescription medications.

Current Use of Information Sources for Use of Non-prescription Medications

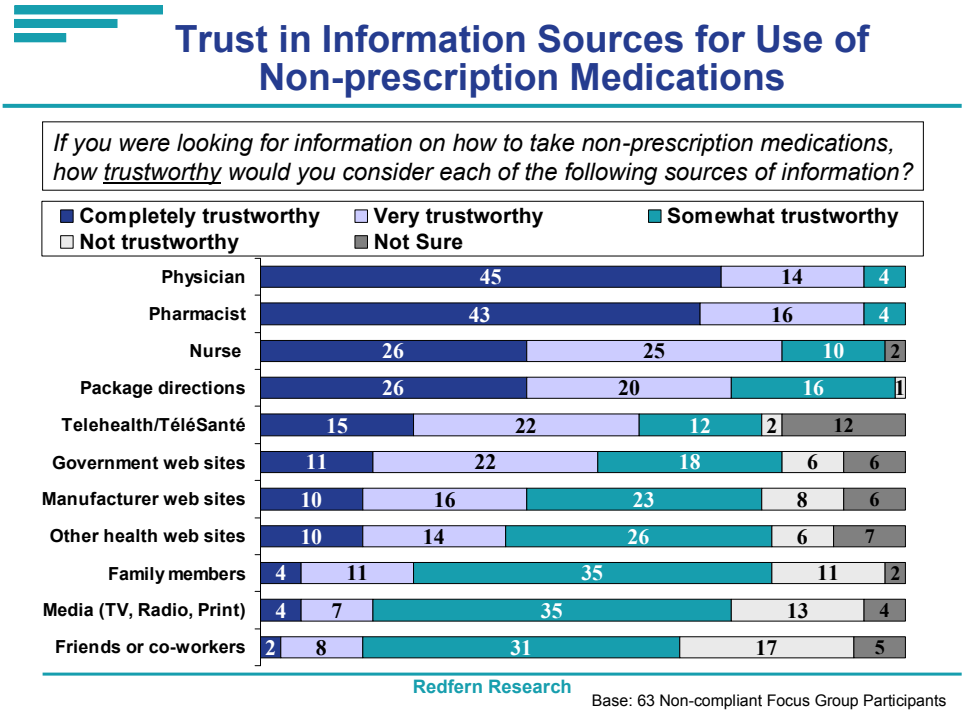
When you think about how to take non-prescription medications, how much do you currently rely on each of the following sources of information?



Base: 63 Non-compliant Focus Group Participants

Asked to rank a number of information sources based on their perceived level of trustworthiness, respondents provide a ranking quite similar to that of the sources they use today. As the following figure shows, physicians and pharmacists continue to top the list, while web sources, friends, family and the media are at the bottom of the list.

A key difference, however, is the relatively low level of trust expressed toward package directions. While non-compliant consumers *use* this information source a great deal, they do not necessarily trust that information. As noted elsewhere in this report, the package directions are assumed to be science-based, but they are also often perceived to be conservative, “one-dose-treats-all” recommendations, influenced by the industry’s desire to minimize legal liability.



Thus, many say that package directions are less than completely trustworthy. Indeed, deliberate non-compliance almost by definition requires that consumers trust their own experience more than they trust package directions. Evidently, physicians and pharmacists maintain considerable authority even with these non-compliant consumers and offer a potential alternative channel of information.

6.2. Concern About Non-compliance

With only one or two exceptions, all of the participants in this study consider themselves *reasonable* and *responsible* users of non-prescription medications, despite the fact that all acknowledge having exceed the Directions for Use. They feel that their non-compliance is a reasonable response to their personal situation and feel vindicated by the fact that they obtain relief and suffer no adverse effects. They might indeed be concerned if asked to take more than the recommended dose of an *unfamiliar* product. But they have developed a level of comfort and experience with their own preferred medications which allows them to feel completely at ease diverging from the Directions for Use. They are, in short, quite unconcerned about their own non-compliant behaviour.

They do express some concern about the non-compliant behaviour of others, mainly because of the possible consequences discussed in Section 6.5. These concerns are especially high if the non-compliance is extreme, chronic, or involves potential interactions with alcohol or prescription medication.

Many believe that non-prescription medications are inherently less dangerous than prescription medications and that only significant misuse of them could cause harm.

6.3. Types of Non-compliance

There are four types of non-compliance demonstrated by the respondents in this study, all of which are predicated on the fact they were undertaken without medical authority[2].

- Excess single dose at one time
- Inadequate time interval after taking maximum dose before taking more
- Exceeding the daily maximum dose
- Using medications for purposes not indicated ("Off label" use)

Of these four types of non-compliant use, the most common by far is the use of an **excess single dose,** ranging from 1.5 to 3 times the recommended amount. Though by no means a frequent behaviour among respondents, many do this occasionally for reasons discussed in the following section.

Out of 63 respondents, only one or two cases were observed where single doses exceeded 1.5 to 3 times the recommended amount.

Among these types of non-compliance, respondents are least likely by far to exceed the **daily dose**. Among the few who do exceed this amount, it is generally limited to 125% or (very uncommonly) 150% of the recommended daily dose. Even among those respondents who may exceed the daily dose, this behaviour is occasional rather than frequent.

"Off label" use often does not initially occur to participants as non-compliance *per se* but emerges instead through extended conversation. Perhaps one respondent in ten acknowledged that they have used ND medications for purposes other than intended. Their objective, always, was to induce sleep. To achieve this end, they may take Gravol or products such as Benadryl and Nyquil. It must be stressed that this behaviour exists when there are no other symptoms of illness (such as nausea or congestion) which would justify the use of the ND.

Very few participants acknowledge breaking the **interval** recommendations on Non-prescription medications. This is far rarer than taking more than the recommended dose as discussed earlier.

One type of possible non-compliance which was not evident in the groups – although probed – was the mixing of incompatible medications. While a small number of participants had mixed

[2] It was very rare in this project to hear that a participant was non-compliant on the explicit instructions of a physician.

medications (such as a pain reliever and a cold remedy) at some point in their lives, this rarely involved a duplication of an active ingredient.

6.4. The Motivations for Non-compliance

In this study, five specific reasons for non-compliance emerged. Most of these relate to suffering and the need for relief.

- Extreme suffering
- Faster relief
- Fear of returning symptoms
- Body Weight
- Assuring Performance
- Bringing on sleep

The following paragraphs discuss each of these motivations, and they are presented roughly in order of the frequency they were mentioned by participants.

Extreme suffering. The most common reason to diverge from package directions, according to participants, is the severity of the symptoms, most often pain or fever. They believe that the recommended dosage of medication will not address their level of suffering, and therefore take an additional amount, usually between 1.5 to 2 times the recommended dose. Suffering is subjective and it is impossible to gauge objectively whether their suffering is truly higher than most or whether the larger dose relieves their suffering more than a regular dose would have. The key fact is that they *believe* both of these things to be true.

Generally, the equation of a larger dose with more complete relief is one borne of personal experience. In the past, they have taken a regular dose and obtained incomplete relief. Thus, they take more. However, it is equally clear that once they 'graduate' to a larger dose, they are not inclined to try the regular dose again to treat the same degree of suffering. In other words, once they start taking larger doses they are likely to continue to do so. This reinforces their personal experience that their suffering justifies larger doses.

Importantly, the reaction to significant suffering is generally to increase the *single dose* rather than shorten the inter-dose interval or exceed the daily maximum. This is instructive, because it confirms the importance of immediate relief. They do not take a regular dose then augment it an hour later if they are not relieved (breaking the interval directions). They are not willing to suffer any longer than they absolutely have to, so they try to "knock down" the symptoms with single excess dose. (It is important for context to recall that these excess doses are generally no more than 1.5 to 2 times the recommended dose.)

One aspect of this reason for non-compliance is the frequency with which it is associated with "migraine" headaches. A significant number of the female respondents who sometimes exceed

the single dose directions on pain relievers say they do so to deal with very painful and persistent headaches. They often use the term “migraine” to describe these headaches.

Faster Relief. There is a subset of non-compliant consumers who genuinely believe that taking more of a medication will bring faster relief. They are quite unlikely to diverge from the prescribed interval or daily dose limits, but will take “extra” medication to obtain faster results. Although this behaviour may be based on a fallacy, it is important to recall that many of these behaviours have been reinforced by experience over time. They believe they have experienced faster relief from a larger dose, and are not disposed to change that behaviour based on a theoretical argument that this benefit is medically unlikely.

Fear of Returning Symptoms. Some non-compliant consumers take additional medication sooner than recommended, because they fear the return of symptoms. Having obtained relief, they do not want to suffer further. For example, if a pain reliever required 30 minutes to provide relief, they will deliberately take it up to an hour before the next interval because they believe their symptoms would otherwise return by that time and they would suffer for another 30 minutes waiting for the next dose to take effect.

Body Weight. The fact that non-prescription dosages are not linked to body weight is noted by perhaps one-quarter of respondents. They doubt that the same amount of medication can be appropriate for people of widely varying weights. Some also note that dosages for children *are* related to body weight. However, no one actually cites this as a reason why they diverge from directions for use, suggesting instead that body weight *would* be a good reason to take more medication than directed. In essence, this reason relates directly to the question of experience. Larger people should, under this logic, experience less relief from the standard dosage and therefore learn over time to take more. In the end, body weight provides an additional rationale - or rationalization - for non-compliance, but this issue is not one which is already in the minds of most non-compliant consumers. It is not a significant *source* of non-compliance.

Assuring performance. Certain situations create anxiety in consumers that, should a non-prescription medication fail to work, they will be placed in a difficult or embarrassing situation. Thus, when they are scheduled to make a presentation, attend a meeting, entertain, get up early, or fly they may take “extra” medication to ensure that they will be able to function. This is a form of insurance and is based on the fear that medications will not work as promised and there will not be time to augment the dose or use other approaches.

Bringing on sleep. Respondents often say that, when they are suffering, they simply want to sleep. They take non-prescription medication to allay symptoms that prevent sleep, but also rely somewhat on the somnolence side-effect created by these medications to hasten sleep. This applies best to cold and flu medications and Gravol, but is also cited for some pain relievers. While somnolence may result from standard doses of these medications, increasing the dose beyond recommended amounts creates a greater drowsiness and the promise of being “knocked out”. Thus, some non-compliance is driven by the desire to amplify the drowsiness

created by non-prescription medications. In most cases, the medications are mainly taken to treat symptoms of illness, but in a few cases, they are taken solely for their ability to aid in sleep.

6.5. Perceived Consequences of Non-compliance

Almost all respondents acknowledge that non-compliance may entail negative health consequences. Yet, there are wide variations in the types and severity of those expected consequences. There is also considerable diversity (and uncertainty) regarding the amount of medication which would cause negative consequences.

6.5.1. Margins of Safety

Most respondents assume that the directions for use printed on non-prescription medications include significant margins of safety. In other words, they believe that most people could safely take more medication than recommended on the package without ill effects. Some assume that the dosages are conservative in order to limit the legal liability of the manufacturers in case of serious adverse reactions. Others assume that the "one-dose-treats-all" approach means that the dosages are necessarily averages which over medicate light people and under medicate heavy people.

There is a great deal of uncertainty about how large these margins of safety actually *are*, however. Almost all respondents believe that their own non-compliant behaviour falls within the safety margins, but they have difficulty defining the precise line where non-compliance becomes unsafe.

When this issue is probed in detail, respondents are clearly guessing. Nonetheless, the following consistent findings emerge. Respondents believe that between 6 and 8 regular Tylenol/Acetaminophen (325mg), taken at one time, would begin to be harmful to the health. They believe between 4 and 9 Advil/Ibuprofen (200mg) in a single dose would be required to damage the health. In both cases, the 'damaging dose' is thought to be between three and four times the recommended dose. The exact 'damage' that might be expected is discussed in the following section.

Remarkably, there is a widespread assumption that users would *know* if they had taken too much of a specific non-prescription medication. Even if they are aware that there could be "silent" damage, respondents repeatedly claim that they have exceeded recommended dosages without ill effects. They assume they would "feel it" if they took too much.

If pressed, many respondents will say that manufacturers *expect* consumers to exceed the recommended dosages on medications. However, these assertions rarely have strength of conviction and this idea was never raised spontaneously by participants. In other words, this idea acts as a useful rationalization for non-compliant behaviour – similar to the issue of body weight – but does not appear to really exist in the minds of non-compliant consumers.

6.5.2. Expected Negative Consequences of Non-compliance

Respondents identify a number of reasons why exceeding directions on non-prescription medications might be unwise, and these are listed in the following paragraphs. Interestingly, three of the most important negative consequences are primarily lifestyle issues rather than medical problems.

- **Addiction**. Excess use of non-prescription medication could lead to dependence, whether psychological or physical.
- **Tolerance.** By overusing a medication, a person may develop a tolerance to that medication, limiting its future effectiveness.
- **Masking another problem.** People using excess non-prescription medication may be masking the symptoms of another, more serious problem.
- **Liver damage.** This was the negative health consequence mentioned most often, always in relation to the overuse of pain relievers, usually Tylenol/Acetaminophen.
- **Unspecified long term effects**. There is an assumption that the overuse of any medication will have long term negative effects on the body. The exact nature of these effects is not clear – respondents often assume they have yet to be discovered by science.
- **Short term digestive problems.** As the first point of contact, the digestive tract is expected by some to react first to excess amounts of medication with nausea, stomach pains, or even ulcers. This is perceived to be especially likely to occur with pain relievers.
- **Short term agitation or drowsiness.** There is an expectation, based partially on experience, that excess amount of non-prescription cold, flu and allergy medication will create drowsiness or dizziness. Antihistamines, in contrast, are sometimes expected to cause agitation or heart palpitations. Both of these effects are seen as amplifications of known potential side effects.
- **Thin blood.** A few respondents mention that excess Acetaminophen “thins the blood.”

With the exception of liver damage, none of these expected effects of non-compliance are either invisible or irreversible. The emerging picture is that the potential impacts of non-compliance are either minor, temporary or treatable.

As noted earlier, respondents cannot distinguish clearly between the normal side effects of a medication, adverse affects such as allergy which might be experienced at any dose, and the specific symptoms created by exceed manufacturer’s directions. A number reported adverse reactions to non-prescription medications but only a few were related to non-compliant use. These included the following:

- Heavy drowsiness due to too much cough syrup.
- Vomiting due to overly strong nicotine patch.
- Weakness due to an excess dose of cold medication syrup.
- Withdrawal headaches after chronic overuse of Ibuprofen

- Severe vomiting caused by stomach flu and/or a mixture of medications used to treat it.

Although each of these five situations was serious for the patient at the time, they represent all the reported lifetime adverse impacts from non-compliant use among 63 focus group participants, all of whom engage in non-compliant behaviour. This is why, for most, non-compliance has no evident downside.

6.6. Changing Non-compliant Behaviour

While consumers are sometimes concerned about the non-compliant use of others, they are rarely concerned about their own divergence from directions. As discussed earlier, they view their own behaviour as reasonable and responsible, based upon experience and self-knowledge. Thus, they are not particularly seized by the question of how government or industry might convince them to change their non-compliant behaviour.

When probed on this question, they do offer five specific suggestions, listed below.

Explain consequences. As noted, non-compliant users are vague about the possible consequences of non-compliance and unclear about the amount of medication which might cause such adverse effects. Many respondents in the focus groups said that the one thing which would change their behaviour would be concrete information about *why* they should comply. In other words, they want to know in clear language what *would likely* happen to they if they fail to follow directions. They state outright that information about consequences, if sufficiently worrying, would change their behaviour. Such information must go beyond a 'laundry list' of possible adverse impacts, because most respondents would assume that those consequences occur only through more serious non-compliance than they pursue themselves, such as extreme doses or chronic non-compliance. They want a clear reason why they should not do what *they* typically do – episodic additional doses of perhaps twice the recommended dosage.

Better format for package warnings. Time and again respondents asked for larger, more readable, more accessible warnings on package which make clear the dangers of non-compliant use. They are looking for a sterner, more explicit warning information which is more evident to users. Some ask for 'alarm formats' such as red fonts and bold fonts. Others ask for visual flags, such as stop signs or even a skull and crossbones.

Advertising and public awareness. Many participants, especially in Québec, felt that there is a place for advertising to impart a pro-compliance message to consumers. Again, this advertising would have to be explicit and specific, containing information about the *likely* consequences of specific types of non-compliance . Often they mention television or billboard advertising.

Pharmacists and pharmacies. Belying once again the supposed importance of physicians as information sources, respondents tend to suggest that pharmacists are well placed to impart information about non-compliance to consumers. This would include personal intervention by pharmacists when confronted with consumers asking questions. It would also include information materials available at the Point of Sale which would provide additional information on the consequences of non-compliance, possibly individualized by the class of medication.

Provide dosage instructions by weight. The "one-dose-treats-all" approach evidently undermines the credibility of dosing instructions on non-prescription medications, creating a disconnect between those instructions and the individual who will decide how much to use. Some respondents say that providing weight-dependent dosing directions would close this credibility gap and lend greater authority to the package instructions.

6.7. Compliance and Children

Consumers claim to apply completely different rules to the use of medication with children than they do to themselves. While everyone in these groups *personally* pushed the boundaries of compliance in some way, they also expressed extreme caution with regard to using non-prescription medications with children. They were reluctant to medicate children and much more likely to consult a physician or pharmacist before doing do. What is more, they claimed to be extremely diligent about respecting directions on non-prescription medications when treating children.

The reasons for this contrasting behaviour were threefold. First, there is a sense that children, being small and undeveloped, are more sensitive to medications overall. Second, there was recognition that small children cannot accurately assess or express their level of suffering either before the medication or after. Thus, adverse effects from the medication may be missed. Finally, there was a heavy sense of responsibility inherent in medicating a child. That relationship is based in trust and protection, and respondents were keenly aware of their responsibilities in this regard.

6.8. Demographic Differences

As noted earlier, these groups were not expected to demonstrate major differences in overall behaviours and attitude between either genders, languages or age groups. In fact, all ages and genders were quite consistent in their discussions of non-compliance. Previous NDMAC research had indicated that rates of non-compliance are similar in all ages groups and in both genders. Nonetheless, some qualitative differences did emerge through the groups, which are noted here.

- Older respondents, drawing on more life experience, were more confident in their medication use and generally less open to additional information or the possibility of change. The idea of long term damage also evidently worried them less. Younger

respondents appeared more likely to listen to information which might change their behaviour.

- Older respondents are also more skeptical of motives. They are more likely to impute ulterior motives to manufacturers (such as avoiding liability or selling more medication) than are younger people.
- Younger respondents tended to be more cavalier about their bodies in general, expressing a lower overall level of fear than older participants. The only examples of 'recreational' or 'experimental' use of non-prescription medications were seen among those 18 to 25. No older person reported such behaviour. There was even a sense that, for young women especially, non-compliance was an expression of independence from parental controls.
- Women generally reported higher suffering than men. This suffering related to menstrual cramps or, more often, severe headaches.
- Quebecers tended to be more relaxed about cold and flu medications which come in the form of syrup. A number said that these products are, for them, associated with candy and are "less serious" than other non-prescription medications.
- TeleSanté was mentioned as a source of information much more often than TeleHealth.

Focus Group Discussion Guide

NDMAC – Non-compliant Use of Non-prescription Medications

July 30, 2007 – Version 3

Guide Summary: Participants are asked what NDs they use, and then discuss whether deviation from ND directions should be cause for concern. They discuss whether there are good reasons to disregard ND instructions and whether the directions for some medications are more critical than for others. Participants then explore the perceived margins of safety in dosing instructions overall and through several examples. Finally, participants discuss the tone and message of package instructions as well as other sources of information on ND use, and explore what information or messages could actually reduce non-compliant use of NDs. On leaving they complete a one-page survey.

Target Length: 90 minutes. 5 or 6 participants.

A. Introduction (5 minutes)

- Welcome participants.
- Focus group process: confidentiality, taping, client viewing.
- Moderator and Respondents' roles.
- Encourage participation. One person speaks at a time. Let everyone speak.
- Cell phones and pagers off. Materials off the table.
- Roundtable of introductions (First name only, family composition)

We have gathered you here tonight to talk about over-the-counter medications, by which we mean This would include *any medication used to treat some medical problem or condition that you can purchase without a prescription, including cold medication, allergy medications, pain medication and stomach remedies.*

B. Warm Up (5 minutes)

1. What types of over-the-counter medications do you buy on a regular basis?

    - Allow unprompted, watch for missing types and probe (eg Tums/Rolaids)

    - Do you still read the label every time you use them, or do you have the instructions memorized now?

C. Perceptions of Non-prescription Medications/ Directions for Use (35 mins)

Instructions on medication packages often specify how much to take, how long to wait between doses, and the total you can take in a day.

2. Where do you think those directions come from? Who writes them?

3. Would you be concerned if you knew a friend or family member did not follow the instructions on an over-the-counter medication?

    - Why or why not?
    - What questions would you ask him/her?
    - What are the potential consequences of not following the instructions?
    - What might he or she tell you that would relieve your concern?
      (Reasonable explanations - Amount/Frequency/Professional advice)

4. Are there reasons to disregard the manufacturers instructions sometimes when taking an over-the-counter medication?

    - What are those reasons?

5. When might you decide not to follow the instructions?

    - What situation would justify a decision not to follow the instructions?
        - Severity/Efficacy/Body weight/Professional advice/Rx substitution?

6. Are some examples of not following instructions more serious than others?

    - What are the less serious situations? When is it okay to 'break the rules'?
    - What are the more serious situations?

7. Are some types of over-the-counter medications more dangerous than others if not used in compliance with directions? [Probe for commonalities if brands mentioned.]

        - How do you know this?

8. If you have a cold or flu and pain as well, is it okay to take cold medicine and pain killers together? Can you give me an example of when it is would be okay/ not okay?

9. Have you ever experienced an adverse reaction to a non-prescription medication when you didn't follow the directions?

10. Do you consider yourselves responsible users of non-prescription medication? Would you say your behaviour is reasonable and makes sense?

11. [PARENTS ONLY] Would you have a different attitude when it came to children and medicine intended for children?

    - How would it be different?

D. Margins of Safety (20 minutes)

12. 1. Do you think there large margins of safety built into instructions for non-prescription medications, or is it dangerous to exceed their guidelines?

    - Which guidelines are the most important to follow? Which are least important?
        - Single dose / Dose interval / Daily dose
    - Do you think the people who write the directions actually *expect* people to take more medication than is recommended or to take it more often?

FOLLOWING SECTION (13/14/15/16) IS ROTATED (TWO QUESTIONS PER GROUP) DEPENDING ON TIME.]

13. For example, the instructions on regular Tylenol/Aspirin/Advil say to take two tablets per dose. How many tablets at one time do you think would be enough to actually hurt you?

    - What could happen to you if you took more?

14. As another example, Nyquil/Dimetapp/Benylin says to take one tablespoon per dose. What amount of in a day do you think would actually create an adverse reaction?

    - What could happen to you if you took more in a day?

15. As another example, Zantac/Pepcid says to take two tablets per day at most. How much Zantac do you think you could safely take without suffering an adverse reaction?

    - What could happen to you if you took more?

16. As another example, Rolaids/Tums says to take two tablets when needed. How much do you think you could safely take without suffering an adverse reaction?

    - What could happen to you if you took more?

E. Messages from Manufacturers and Medical Professionals (20 minutes)

17. Thinking about the package instructions on over-the-counter medications, what kind of message do they send about following the dosage guidelines? Do they make it seem really important, or more of a suggestion?

- What makes you say that?
- How can you tell when the dosing limits are really important?

18. Besides the packages, what other sources of information have you used about how to use non-prescription medications?

- Has anyone – such as a health care professional like a doctor or nurse - ever spoken to you about following the directions on over-the-counter medications?
  - What did they say?
  - Did you take what they said seriously?
- Has anyone else ever spoken to you?

19. If the manufacturers of over-the-counter medications wanted you to take their directions more seriously, what could they do?

- Other spokespeople? (Who would you trust/listen to?)
- More specific warnings?
- Different wording/format on the packages?
- Explain the consequences?

F. Conclusion (5 minutes)

20. The manufacturers of over-the-counter medications really want consumers to always use their products responsibly. Before we finish, we're going to go around the table, and ask you to write down your best advice to them on how they might convince people like you to always follow the directions. Then we will go around the table and share what you wrote down. [ROUNDTABLE]

- Based on what you've heard today and elsewhere, what one thing should they definitely do or what should they definitely not do?

On behalf of Redfern Research, I want to thank you for coming today and sharing your opinions.

Post-group Questionnaire

Please answer the following questions by ticking the box which matches your opinion.

1. When you think about how to take non-prescription medications, how much do you currently rely on each of the following sources of information?

	Major source of information	Minor source of information	Not a source of information	Not sure
Package directions	☐	☐	☐	☐
Physician	☐	☐	☐	☐
Nurse	☐	☐	☐	☐
Pharmacist	☐	☐	☐	☐
Family members	☐	☐	☐	☐
Government web sites	☐	☐	☐	☐
Manufacturer web sites	☐	☐	☐	☐
Other health web sites	☐	☐	☐	☐
Friends or co-workers	☐	☐	☐	☐
Media (TV, Radio, Print)	☐	☐	☐	☐
Telehealth	☐	☐	☐	☐

2. If you were looking for information on how to take non-prescription medications, how trustworthy would you consider each of the following sources of information?

	Completely trustworthy	Very trustworthy	Somewhat trustworthy	Not trustworthy	Not sure
Package directions	☐	☐	☐	☐	☐
Physician	☐	☐	☐	☐	☐
Nurse / Telehealth	☐	☐	☐	☐	☐
Pharmacist	☐	☐	☐	☐	☐
Family members	☐	☐	☐	☐	☐
Government web sites	☐	☐	☐	☐	☐
Manufacturer web sites	☐	☐	☐	☐	☐
Other health web sites	☐	☐	☐	☐	☐
Friends or co-workers	☐	☐	☐	☐	☐
Media (TV, Radio, Print)	☐	☐	☐	☐	☐
Telehealth	☐	☐	☐	☐	☐