

**Docket No. 02N-0209--Request for Comment on First Amendment Issues--  
Do they (DTC ads) lead to adequate patient understanding**

**of the potential risks associated with the use of drugs?** 11 29 P1:17

**Which Prescription for the Illegible and Unreadable DTC Brief  
Summary--Major Surgery or Euthanasia?**

Mark Hochhauser, PhD  
Readability Consulting  
3344 Scott Avenue North  
Golden Valley, MN 55422  
Phone: (763) 521-4672  
Fax: (763) 521-5069  
E-mail: MarkH38514@aol.com

Mark Hochhauser, Ph.D.  
Consultant



**Readability Consulting**  
How readable is your writing?

3344 Scott Avenue North  
Golden Valley, MN 55422

Email: MarkH38514@aol.com  
Phone: (763) 521-4672  
Fax: (763) 521-5069

**Abstract:**

Health care costs are rising, mostly because of increased prescription drug use, chiefly as the result of Direct-to-Consumer (DTC) drug ads on television, newspapers, and magazines. However, the FDA's requirement for a brief summary in DTC ads has produced summaries that are ineffective because they are illegible and unreadable, create information overload, and require literacy skills not possessed by most consumers. If the FDA wants brief summaries to be in a patient-friendly format, it should provide document design templates and plain language examples. Unless brief summaries are written so that they can be understood by the average patient, they should be overhauled or done away with.

**Text:**

Healthcare costs are rising, at least in part because of heavy direct-to-consumer (DTC) drugs ads on television, and in newspapers and magazines. DTC ads are supposed to provide consumers with useful information about prescription drugs so they can talk to their doctors about their health problems and the drugs they might need. The question is, can consumers make an informed decision based on the drug ad (written by marketers) and the accompanying "brief summary" (written by medical staff, probably with input from the legal department)? Are some consumers asking their doctor for a drug, not out of knowledge but out of ignorance?

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In a recent summary of studies done on DTC ads, the Coalition for Healthcare Communication ([www.cohealthcom.org](http://www.cohealthcom.org)) reported that in a 1999 study, 31% of respondents claimed to have read the brief

summary, with 48% of those saying they had read all of it. Another 1999 study found 8% of respondents saying they had read almost all of the Brief Summary in print advertising, while a 1997 survey found 32% claiming to have read almost all of the Brief Summary.

Even if an unlikely one-third of consumers are actually reading brief summaries, no more than a handful can understand what they are reading. That's because the typical brief summary is full of medical and technical jargon and written in long sentences containing big words. In addition, most brief summaries are printed in type too small for the average person, especially seniors, to read.

### **Brief summaries are illegible**

Although standard document design texts recommend about 40 characters per line and about 8 to 12 words per line, one brief summary printed recently in *Newsweek* held about 38 characters per inch--as many as 24 words per line, with 100 lines on the page. Even that grim analysis may be a little misleading: The summary had only 24 words per line because so many of the words were lengthy medical terms. Further, the word print in this summary was so dense that I had to increase its size on my copier to 200% to see it well enough to type it into my word processor for a readability analysis. (See Table 1.)

This particular brief summary had two columns of compressed (justified) text with no paragraph breaks. Each column ran the full length of the page, about 4,000 to 5,000 words on one page, or 13 lines per inch. In comparison, a typical news article in the magazine is far more legible, as it has about 6 lines per vertical inch.

In comparison, the May issue of *Reader's Digest* carried 10 DTC ads. Eight were of the traditional brief summary format. One was labeled "Patient Information" and the other, "Patient Summary of Information." The latter two were written in a more legible format than the brief summaries. Both used a question-and-answer format, summarized with bullet points, and utilized more white space to aid legibility. Two DTC "Patient Summary" ads from the May issue of *Parents* magazine were written at about a high school reading level, a big improvement over the obtuse medical jargon.

Hoping that other legible versions of brief summaries might be available online, I visited the Web sites of some drug companies. Some of the Web sites tried to be helpful, as they provided information about their drugs in a question-and-answer format. However, none of the Web sites I checked presented any brief summaries of products. They did provide a category called

"complete prescribing information," but some of those documents (usually in PDF format) were as long as 28 single-spaced pages.

None of the magazine DTC ads I reviewed listed any Web sites. Some ads told readers that "If you would like more information, ask your doctor or pharmacist to let you read the professional labeling and then discuss it with them." Or "For full Prescribing Information see package insert." The full prescribing information is just like a brief summary--only it's generally twice as long.

### **Brief summaries overmatch the literacy skills of most consumers**

Recent census data show that about 84% of adults have a high school diploma, while about 26% have a college degree or postgraduate degree. But college students can major in anything from A(rt) History to Z(oo)logy, and not everyone with a college degree graduates with the same vocabulary. While biology majors might be able to understand some parts of the brief summary, graduates from most other disciplines will be completely mystified.

Based on Census Data from March 2000, Table 1 summarizes the educational attainment of all adults, and for those age 65 and older.

**Table 1: Adult Educational Attainment  
(March 2000 Census Data)**

		Selected age groups					
	all adults	25-54	55-59	60-64	65-74	75-84	85+
Less than 9th grade	7%	4%	7%	10%	13%	19%	29%
9th-12th grade/no diploma	9%	7%	9%	12%	13%	14%	14%
High school graduate	33%	32%	35%	36%	37%	35%	30%
Some college/Assoc. Degree	25%	28%	24%	21%	19%	18%	14%
Bachelor's Degree	17%	20%	14%	12%	10%	9%	9%
Advanced Degree	9%	9%	11%	9%	7%	5%	4%

Note that the percentages of adults with college degrees drop with age, and older adults have far less formal education than do younger adults. Comparing educational attainment with the reading grade level of brief summaries suggests that most patients--especially the elderly--will have a hard time reading and understanding them. Many of the DTC ads target the elderly, yet the brief summary is written in ways that make it completely inappropriate for most elderly patients to digest the information.

Plus, literacy research shows that people often read 3 to 5 grades lower than their highest level of educational attainment. Because a typical high school graduate may actually be reading at a 7th to 9th grade reading level, most literacy researchers

recommend that materials written for the general public be written at a junior high reading level--about 8th grade.

Is it possible to take a brief summary written at a graduate school reading level and re-write it at a junior high reading level? It is possible. One of the Patient Summaries (in *Parents* magazine, mentioned earlier) was at a junior high reading level, and another example was at a high school reading level. Unfortunately, only these two out of the ten summaries reviewed could be considered written in consumer-friendly language.

The 1993 National Adult Literacy Survey (NALS) measured prose literacy (skills needed to understand and use information from texts), document literacy (skills needed to find and use information in forms and schedules), and quantitative literacy (arithmetic skills). On a scale from 0 to 500, high school graduates had an average prose score of 270 (interpreting instructions from an appliance warranty). People 65 and older had an average prose score of 230 (underlining the meaning of a term given in a government brochure on supplemental security income).

The NALS had five literacy levels--about 50% of the adult population was in the two lowest levels--22% in level 1 and 27% in level 2. There is a large gap between the literacy skills possessed by the adult population and the literacy skills needed to understand a brief summary.

### **Brief summaries are indecipherable**

Given the preceding analysis, how likely is it that the average consumer will understand concepts such as AUC (which I could not find defined anywhere), contraindications, prophylaxis, mutagenesis, teratogenic effects, genotoxicity, adverse reactions (endocrine, hematologic, hepatic, etc.), adverse events (pharyngitis, myalgia, somnolence, dysmenorrhea, asthenia) placebo controlled trials, pruritis, bioavailability, etc.? Brief summaries are usually not written in plain English. They are full of medical, technical and scientific language that is unfamiliar to most consumers. Reading a brief summary requires having a medical dictionary at hand and the willingness to use it many times to try to decode the technical language.

In his 1949 book "*The Art of Readable Writing*," Rudolf Flesch summarized some basic statistics for various grade levels. Table 1 is a comparison of Flesch's statistics with six "brief summaries." I typed in 500-600 words for each Brief Summary and Patient Summary of Information, and used readability software to calculate the readability statistics and to compare them with Flesch's statistics for materials written in a "fairly easy" or "standard" writing style.

For the Flesch Reading Ease Score, 0-30 = very difficult; 30-50 = difficult; 50-60 = fairly difficult; 60-70 = standard; 70-80 = fairly easy; 80-90 = easy; and 90-100 = very easy. Most readability software programs do not score beyond a first-year graduate school (Grade 17+) reading level.

**Table 2: Flesch Readability Analysis**

Brief Summaries	Flesch Reading Ease	Grade Level	Scale of Complexity (100=Most Complex)*	
			Sentence	Vocabulary
Summary #1	16/Very Difficult	17+	56	70
Summary #2	15/Very Difficult	17+	64	70
Summary #3	26/Very Difficult	16	61	66
Summary #4	16/Very Difficult	17+	73	71
Summary #5	16/Very Difficult	17+	51	73
Summary #6	19/Very Difficult	17+	54	70
<b>Average</b>	<b>18/Very Difficult</b>	<b>17</b>	<b>60</b>	<b>70</b>
<b>Patient Summary of Information</b>				
Summary #1	42/Difficult	13-14	27	45
Summary #2	55/Fairly Difficult	11-12	39	34
Summary #3	49/Difficult	12-13	37	58
Summary #4	68/Standard	8-9	22	22
<b>Average</b>	<b>54/Fairly Difficult</b>	<b>11-12</b>	<b>31</b>	<b>40</b>

\*Using Grammatik 6.0, Sentence Complexity is based on the average number of words and clauses in the Brief Summary. Vocabulary Complexity is based on the average number of syllables and a comparison of word choice to a list of unusual or difficult words.

The readability software suggests that the six brief Summaries are hard to read largely because of too many words per sentence, too many syllables per word, and too many unusual words. In long sentences, readers may forget the beginning of the sentence by the time they get to the end.

One way to make the brief summaries more readable (at least statistically) is to write shorter sentences with shorter (more common) words. But making a brief summary more readable does not guarantee that consumers will have a better understanding. However, of the four "Patient Summary of Information" samples, two (#4 and #2) were especially well designed and written, and could serve as a model for other pharmaceutical company writers.

#### **Brief summaries create information overload**

Another factor that affects understanding is the sheer amount of information presented in a brief summary, and the ability of an average consumer to process that information. Our "working memory" is limited to the amount of information we can keep in

our memory and process at the same time. Although early research suggested that working memory could hold from five to nine items, current research suggests that three to five ideas is more likely. When people feel overwhelmed by information they often show increased stress, confusion, impaired judgment, helplessness, and paralysis through analysis. Too much information makes it harder (maybe impossible) to make a decision--not easier.

Context also is critical. Information that's not put into a meaningful context is little more than raw data. Although it meets FDA requirements, a typical brief summary stated that "Additional adverse events that were reported as possibly or probably related to [this drug] with an incidence <1% are listed below by body system..." What follows is a list of 139 possible/probably adverse events. Are any of these adverse events serious? Trivial? Which ones should I be concerned about? Which ones are possibly related? Which ones are probably related? Which ones should I ignore?

What conclusion should a reader get from this list? My conclusion is that if these adverse events happened to fewer than 1% of patients, then I'm going to ignore them. Why even list them? Of what real value is this mere listing of adverse events?

#### **Fix the Brief Summary or abandon it**

FDA documents list certain goals for drug summaries:

- "...communicate in understandable language the most important information patients need to use the product appropriately"
- "...providing benefit and risk information in a form understandable to consumers..."
- "encourages sponsors to consider the benefits of also providing consumers with nonpromotional, consumer friendly product information."

However, the FDA does not define "understandable language," "understandable to consumers," or "consumer friendly product information," nor does it give examples of language that would meet those criteria or suggest what evaluation methods could be used to determine whether consumers viewed the brief summary as "understandable" or "consumer friendly."

Of course, the pharmaceutical industry will argue that it's just following FDA requirements for a brief summary--which is true. But although the FDA does mandate the topics to be covered in the Brief Summary, the FDA does not require that the Brief Summary be written in an unreadable and illegible style. There is no compelling reason that Brief Summaries can't be written in a more

patient-friendly format, except that it's (and perhaps legally safer) to reprint FDA approved language than it is to develop consumer friendly (but not FDA approved) language.

If the FDA wants the pharmaceutical industry to publish Brief Summaries in a patient-friendly format, then the FDA should provide document design templates and plain language examples for the pharmaceutical industry to follow, perhaps through conference presentations, training workshops, online documentation, etc. It's easy to recommend that brief summaries be written in "understandable language," but it's very hard to write them that way if writers are used to writing in a scientifically and technically complicated style. Writing at a junior high reading level does not come easily if all your writing experience is at a graduate school reading level.

The current system involves a government agency requiring brief summaries, and a pharmaceutical industry providing them to meet that requirement. Unfortunately, meeting the federal requirement is necessary, but not sufficient. If brief summaries cannot be written in a style that can be understood by the "average" patient (like the patient summary written at a 8th-9th grade reading level), then it's time to do away with brief summaries. There's no point in giving patients information they can't read or understand just to satisfy government regulations.

Mark Hochhauser, PhD, is a Readability Consultant in Golden Valley MN. Contact Mark Hochhauser at (763) 521-4672 or [MarkH38514@aol.com](mailto:MarkH38514@aol.com)

[Sidebar]

### **Some Suggestions for Measuring Readership of Brief Summaries**

One way to estimate how many people read the Brief Summary is for pharmaceutical companies to ask doctors and pharmacists to answer these questions:

How many patients ask for "Full Prescribing Information?"

How much time is spent discussing the Brief Summary/Full Prescribing Information with the patient?

Given the national shortage of pharmacists, and the limited amount of time physicians have for patients visits, probably little (if any) time can be spent discussing the details in 28 pages of "Full Prescribing Information."

There are other methods of determining readership. For example, drug companies could imbed a statement near the middle or end of the Brief Summary informing readers that if they call an 800

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number, they will be entered in a raffle to win a valuable prize. By keeping track of how many people phone in, drug companies will know how many people actually read the Brief Summary, at least as far as the notice about the raffle. I am willing to bet that the cash outlay for prizes (if any) will not dent the drug companies' bottom line.

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Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Room 106  
Rockville, MD 20852

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