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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2004N-0221: Comment on Making Prescription Pharmaceutical Information Accessible for Blind and Visually-Impaired Individuals

Dear Sir or Madam:

I am writing in two capacities: 1) as a researcher with expertise concerning the reading difficulties of people with impaired vision, and 2) as an individual with impaired vision myself.

The mandate to make prescription pharmaceutical information accessible to visually impaired people is very important, and relevant to the health of several million Americans.

Background Resources

I recommend that you consult two National Research Council reports published in 1995 and 2002, cited in the references below. The 2002 report was prepared at the request of the Social Security Administration, and deals with the impact of vision disability on reading, mobility and other activities bearing on employment. This report reviews in detail the demographics of vision loss in the U.S. population, including socioeconomic factors and employment rates.

The 1995 report was prepared at the request of the Treasury Department, and deals with accessibility of U.S. currency bills by visually disabled people. Many of the issues related to use of currency are applicable to other documents, possibly including pharmaceutical labeling and information.

I served on both of these NRC committees and was a co-author of the two reports.

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Population to be Served

The Eye Diseases Prevalence Research Group has published a definitive series of articles in the April 2004 issue of *Archives of Ophthalmology*, providing the best contemporary estimates of the prevalence of vision impairment in the U.S. I have cited the most relevant article in the reference list below.

Their analysis applies to people over 40 years of age. The estimates include most of the visually impaired population because the large majority of vision disability arises from age-related eye diseases (macular degeneration, glaucoma, cataract, diabetic retinopathy). On the other hand, the restriction to people over 40 means that their numbers underestimate the total population of visually impaired people. Here are some summary figures drawn from this analysis:

- Prevalence Estimates: There are 937,000 legally blind people, and another 2.4 million with milder low vision, making a total of about 3.3 million Americans over age 40 with vision impairment.
- Projections: By the year 2020, demographic trends predict an increase in these numbers by about 70%, bringing us close to 5.7 million Americans over the age of 40 with impaired vision.
- Racial Differences: The leading cause of visual impairment among whites is age-related macular degeneration (54.4%). For blacks, cataract and glaucoma account for more than 60% of the visually impaired population.

It is important to recognize that these numbers represent a spectrum of vision disability ranging from total blindness (no light perception) to mild visual impairment. There are roughly 200,000 to 300,000 people who are totallyGordon E. Legge Page 2 6/18/2004 blind or have no useful pattern vision. The large majority of the visually impaired population have at least some functionally useful vision.

It is widely understood that almost everyone with impaired vision has difficulty reading print. In particular, the large number of people with central visual-field loss from age-related macular degeneration have severe reading problems. While magnification of print using magnifiers or large-print fonts is helpful, many people with impaired vision have reading problems even when they are prescribed suitable magnification. The reason is that impairment from visual-field loss or reduced contrast sensitivity cannot be fully compensated for by magnification.

It should also be noted that even people with healthy eyes will encounter reading difficulties under challenging viewing conditions such as low illumination. This is especially true of older adults whose visual acuity under low illumination (e.g., poorly illuminated home environment) may be compromised to some degree.

Methods for Accessing Text

People with the mildest forms of vision impairment are often able to read regular printed text, provided that 1) the lighting and other viewing conditions are good, 2) the text is printed in a standard font and type size, and 3) page layout is simple. This group may benefit from a version of the text printed in a "large print" font such as 18-point Arial.

Many people with moderate low vision are able to read regular print with an optical magnifier. Typically, magnifiers are prescribed by eye-care clinicians to meet a patient's reading goals. A common criterion is to prescribe a magnifier to read the newspaper. DeMarco & Massof (1997) have surveyed the distribution of print sizes in a wide range of newspapers. An average print size corresponds to an x-height of 1.45 mm (1.0 Sloan M units). This print size should be regarded as an absolute lower bound on the print size accessible to magnifier users. Under no circumstances should important prescription drug information be printed in a smaller type size. It should also be kept in mind that many magnifier users will not be successful in reading newsprint.

Some people with more severe forms of low vision cannot read regular print with optical magnifiers, but can read with electronic magnifiers. The most successful form of electronic magnifier is the Closed-Circuit TV (CCTV) magnifier. The reader places text beneath a video camera and highly magnified text appears on the TV monitor. With the help of zoom lenses, CCTV magnifiers can enlarge text by at least 40X. While the CCTV has been very important for people with low acuity, it is costly ($1,000 to $2,000) and typically not portable. Recent innovations in portable electronic magnifiers are promising. Nevertheless, many people with impaired vision (e.g., elderly people on fixed incomes) cannot afford a CCTV magnifier, even though it could be helpful to them.

An important innovation has been the development of screen-magnification software programs for enlarging print on computer displays. An example is ZoomText (AI-Squared, Manchester VT). This software allows many people with mild or severe impaired vision to read text on a computer display. But even with screen-magnification software, visually complex screen layouts (e.g., complicated web pages or software menus) can be difficult or impossible to use. As with print on paper, simple layouts improve computer access.

People who are blind or have the most severe forms of low vision rely on non-visual methods for reading—Braille, audio, or reading aloud by a sighted assistant. These three methods all require intervention by a sighted person (e.g., a transcriber who converts printed text to Braille) and therefore limit direct access to print. People who rely on these methods, do not have quick and reliable access to print. In such cases, easy access to prescription drug information is not currently possible.

Modern technology offers several methods for non-visual access to print without the help of a sighted person:

- Synthetic Speech on Computer: Screen-reading programs such as JAWS (Freedom Scientific, St. Petersburg, FL) convert computer-based text files to synthetic speech. A visually impaired person can listen to text in a Word document, pdf document or html document on the web. Most standard computer-based text formats can be accessed by synthetic speech.
- Braille Translation Programs. Computer-based text documents (such as a Microsoft Word document) can be processed by a Braille translation program, and the output sent to a Braille printer. The output can be read by anyone who knows Braille. Although Braille is of enormous benefit to many people with severe visual impairment, many people who lose their vision late in life do not use Braille.
- Computer-Based Optical Character Recognition (OCR): Relatively inexpensive software can be used in conjunction with a scanner to convert printed text on paper into a text document on a computer. The success of the OCR process is enhanced if the original printed text has high quality print in a simple page layout. Once the text is converted into a digital format, the document can be accessed by one of the two methods just described—synthetic speech or Braille output.

Recommendations for Accessing Prescription Drug Information

Given the above considerations, I offer the following recommendations for making prescription drug information accessible to people with the wide range of vision impairments and reading needs discussed above:

1) For people with mild vision impairment, who rely on direct visual access to printed drug information:

A panel of experts, to include vision rehabilitation specialists and typographers, should establish minimum standards for printed prescription drug information. The minimum print size should not be less than 1.45 mm (x-height) and should most probably be larger.

2) For people who would benefit from alternative formats of text:

Prescription forms used by physicians should include a set of options such as the following:

"Provide Information to the patient in an alternative format (check one):
__ Large Print
__Braille
__Audio cassette.

The pharmaceutical companies would be responsible for providing these materials to the patient on a per-request basis. The request would be submitted via the web by the pharmacist filling the prescription. The expectation would be that the drug company would fill the request for the information in the requested alternative format and send it directly to the patient in a timely manner. Given the relatively modest volume of such requests, and the relatively minor cost of production, the costs to the pharmaceutical companies will be modest.

3) For people with vision impairments who have web access:

As I described above, screen reading software (JAWS) and screen magnification software (ZoomText) have enhanced computer access for visually disabled people. Drug companies should provide information about their products on the web in a speech-friendly and screen-magnifier-friendly format. Preferably, the user could log into a single website and use an easy Search method or menu system to find information on specific prescription drugs.

In principle, the same website could be used by pharmacists to request information in "alternative formats" for their customers (see #2 above) and by visually-impaired people seeking their own information.

It is important to recall that many people (especially older people) do not own computers, or are not skillful in web access. In addition, the demands of learning and using adaptive software, such as JAWS and ZoomText, are substantial, and outside the capabilities of many visually impaired people. For this reason, strict reliance on web access to prescription drug information will bypass many people.

Finally, it may be worth considering an 800-number telephone service that would provide prescription drug information using an automated service. Voice-activated menus (like those used in Airline Reservation systems) might be used to access pre-recorded information on specific drugs. Almost everyone has access to a telephone. Pharmacists could provide their customers with information about the 800 service. Provided the user has normal hearing and language capability, the phone service might be a viable alternative to a web-based source of information.

References

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National Research Council (2002). *Visual Impairments: Determining Eligibility for Social Security Benefits.* Prepared by the Committee on Disability Determination for Individuals with Visual Impairments, National Academy Press.

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Thanks you for considering these comments.

Yours sincerely,

Gordon E. Legge, Ph.D.
Distinguished McKnight University Professor