

From: Gary Christopher Norman, Esq.  
Maryland Area Guide Dog Users, Inc.  
10 Breton Hill Rd.  
Apt 1B  
Baltimore, MD 21208  
(410) 786-6256

7477 04 JUN 14 19:30

Date: June 2, 2004

To: Division of Dockets Management, (HFA-305)  
US Food & Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
<http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html>

**SUBJECT: PUBLIC COMMENT ON DOCKET NO. 2004 N-0221 REGARDING  
MEDICARE PRESCRIPTION DRUG, IMPROVEMENT & MODERNIZATION ACT  
OF 2003.**

My name is Gary Christopher Norman, Esq. I am an attorney who works with a guide dog and serve as president of a new non-profit named, the Maryland Area Guide Dog Users, Inc (MAGDU). I write on behalf of my organization to comment on the efforts or requirements can be taken to ensure the disabled community's access to prescription drug information.

While our organization welcomes this statutorily mandated study of accessibility of prescriptions, law and policy governed under and implemented through the Americans With Disabilities Act of 1990 and, the Rehabilitation Act of 1973, require the equal access of persons with disabilities to this important health care information. Our organization, an affiliate of the Guide Dog Users, Inc., and the American Council of the Blind of Maryland desires to emphasize the degree to which the US Department of Health & Human Services (DHHS) should enhance its civil rights enforcement efforts in this regard. Once again, however, our organization welcomes this study to the extent that recommendations fostered from its findings will either strengthen enforcement measures or furnish helpful technical assistance to prescription Providers.

#### **SIZE OF THE POPULATION AND SCOPE OF THE PROBLEM**

Persons with disabilities represent a significant population, equaling some 54 million individuals<sup>i</sup>. As noted in one health care publication, persons with disabilities constitute a vulnerable heterogeneous group possessing substantial access issues to health care facilities, services and programs.<sup>ii</sup>

Common causes of blindness or visual impairment comprise complications to other chronic conditions, such as Diabetes Mellitis and Hypertension, genetic birth defects and injuries. An organization focusing upon sight impairment issues, which is named Alabama Industries for the Depth & Blind (AIDB), quotes data from the National Federation of the Blind that estimates blindness affects 50,000 new individuals each year. Vision loss particularly affects the aging population, children and those with multiple disabilities.

The number of persons experiencing severe vision loss will exponentially increase in the United States as the "baby boom" generation achieves senior citizen status. AIDB cites data from the

National Aging & Vision Network, who argue that all persons will eventually suffer some level of vision loss, and 4 million individuals fifty-five (55) years or older experience severe vision impairment<sup>iii</sup>. Almost 4.9 million Americans suffer severe visual impairment; a number that many estimate will double in the next 30 years<sup>iv</sup>. To address the issue of blindness onset secondary to aging, myriad blindness advocacy organizations and rehabilitation agencies are undertaking outreach measures to the elderly blind population. In addressing accessibility issues, the elderly blind constitutes a population that should receive particular consideration.

## COMMENTS AND RECOMMENDATIONS

As a reputable British medical journal argued, access to health care services, programs and information falls under the purview of fundamental human rights<sup>v</sup>. Institutional barriers and discrimination have denied blind or visually impaired persons access to health care services, programs and information for too long. Providers and Manufacturers need to recognize their obligations under the ADA and Rehabilitation Act, to address the needs of blind or visually impaired patients and make prescription information available in alternative formats, such as large print, Braille or via the Internet and disk. In an age like no other, when so myriad techniques, tools and options exist to facilitate meaningful access, no justifiable reason exists why prescription Providers and Manufacturers should continue their exclusionary practices. Advances in technology that have facilitated the increasing inclusion of persons with disabilities into the workforce can also ensure equal access to health care information. Moreover, Providers can rely on even older but more common forms of technology, such as telephone hotlines and Braille to ensure equal access to prescriptions. Blind or visually impaired people should be able to obtain prescription information via their preferred format without additional expense<sup>vi</sup>. A number of sources, such as pharmacies, doctors, or nurses can inform patients of the availability of alternative formatted information. Further, despite any undue burden or financial hardship defenses or assertions that Providers might claim, facilitating and accommodating access can be accomplished with relative low cost and to their pecuniary gain.

First, a cheaper way by which prescription Providers and manufactures can facilitate and accommodate meaningful access consists of incorporating "universal design" into existing technologies. This means a concept or philosophy for designing and delivering products and services usable by the widest number of persons either directly and without assistive technology or incorporates and envisions its interface with assistive technologies.<sup>vii</sup>

Universal design beneficially affects Providers and manufacturers as well as a multiplicity of users, including, those who are non-disabled but suffer from Low English Proficiency (LEP). Universal design constitutes prudent business sense, because adopting these designs often results in limited cost. Designs, which are accessible to people with disabilities typically, benefit able-bodied users as well by reducing fatigue, increasing speed and decreasing the number of errors. Through deliberate and informed planning, universally designed features tend to require less strength, agility, mobility, coordination, cognition, and accuracy to accomplish the same task. Universal design can not only increase the marketability of products to people without traditional limitations, but it can also create market access to a potentially large population of people with varying disabilities<sup>viii</sup>. Our organization recommends that prescription Providers and manufacturers design prescription containers and information in a manner, allowing accessibility to the largest number of persons, including, those with LEP. Providers and manufacturers can consider implementing this recommendation by:

- Furnishing information in simple English

- Using matte rather than glossy paper to reduce glare and facilitate reading ease, and potentially, improve the quality of its scanning
- Furnishing information in larger and clear fonts, and
- Furnishing information that has contrast between the background of the paper and lettering, e.g., white background with large black lettering.<sup>ix</sup>

The second medium through which prescription Providers and manufacturers can ensure the accessibility of prescription information, includes, the provision of instructions and other details in large print and Braille. Generally, for all persons, disabled and non-disabled alike, Providers and manufacturers should consider furnishing an informational leaflet concerning dosages, usage instructions, as well as risks and side effects. The United Kingdom (UK) has commenced the practice of accompanying informational leaflets with prescriptions, a practice that would reap similar preventative effects against the alarming number of medical errors in the United States<sup>x</sup>. The provision of larger print fonts, sixteen or eighteen point bold face, will not only serve the truly visually disabled, but also foster universal design by allowing the aging population greater reading ease. While, assistive technologies in the way of screen reading software has expanded information access to the blind or visually impaired, Braille still constitutes a vital means of accommodation to the printed word<sup>xi</sup>. Technology, such as software and hardware that allow the translation of documents into Braille code, and thereafter, its printing through a standard desktop computer has like no other age in history made Braille readily available. While, a national issue of Braille literacy plagues the sight impaired community; the provision of prescription information in a Braille format to requesting persons, will comprise an important way by which Providers and manufacturers can accommodate the blind or visually impaired. Our organization recommends accommodating the sight-impaired community, and, even those who might not be considered blind under the legal definition, but suffer from vision loss secondary to advance years, through the mediums of large print and Braille.

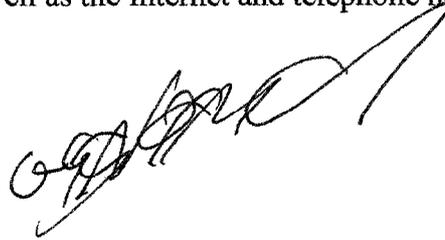
The third and final means through which prescription Providers and manufacturers can ensure accessibility to prescription information, includes, the application of informatics and Internet technologies. A prescription container that has the ability to play an audio recording of information presently exists<sup>xii</sup>. Providers and manufacturers can parlay their group purchasing power to reduce these already relatively low-cost devices to ensure accessibility to the blind or visually impaired. Screen-reading technology, legal requirements and a movement to design websites in an accessible format have enhanced the access of blind or visually impaired persons to the information age, thusly, ever increasing numbers of this population obtain and use information through the medium of the Internet. Providers and manufacturers can ensure accessibility to prescription information by erecting compliant WebPages that contain information relative to what a sighted individual receives when furnished a prescription. Yet, a digital divide does exist within the disability community. In the alternative, Providers and manufacturers can ensure accessibility to prescription information by establishing a telephone hotline that would provide the same information a sighted person receives when furnished a prescription<sup>xiii</sup>. Our organization recommends these tools for the accommodation of the blind or visually impaired.

## CONCLUSION

Our organization desires to express its pleasure for the opportunity to furnish the foregoing comments and recommendations. First, our organization emphasizes the need for greater civil rights enforcement against violations of applicable disability law and policy by prescription Providers and manufacturers. Second, a range of approaches can ensure accessibility of

prescription information. While, one approach cannot meet the needs of all blind or visually impaired persons, to the extent that Providers and manufacturers incorporate universal design into the provision of information, both the needs of the visually disabled and the non-disabled population will benefit. Third, while Providers and manufacturers will most likely object to any additional legal or policy requirements the federal government establishes and enforces, most accommodations can be implemented with relative low-cost; and to the extent such measures enhance access to this population, a new market and source of revenue will open. Finally, Providers and manufacturers should provide prescription information through such mediums, such as large print and Braille, as well as the Internet and telephone hotlines.

CC: Poppy Kendall  
 Office of Policy, (HF-11)  
 US Food & Drug Administration  
 5600 Fishers Lane  
 Rockville, MD 20857  
 E.: [poppy.kendall@fda.gov](mailto:poppy.kendall@fda.gov)



<sup>i</sup> Center for Universal Design & the NC Office on Disability & Health, Removing Barriers to Health Care: A Guide for Health Care Professionals, [www.design.ncsu.edu/cud](http://www.design.ncsu.edu/cud).

<sup>ii</sup> Id.

<sup>iii</sup> Alabama Industries for the Deaf & Blind, Information on Blindness, (2004), [www.aidb.org](http://www.aidb.org).

<sup>iv</sup> Edwin Zebelski, Civil Rights Issues Facing the Blind & Visually Impaired in Illinois, (May 29, 1998).

<sup>v</sup> B. Med. J., Medicines Information – Leaving Blind People Behind?, No. 7103 Vol. 315 (Aug. 2, 1997).

<sup>vi</sup> The Americans with Disabilities Act of 1990, 42 USC §12101 et seq., and its implementing regulations require this.

<sup>vii</sup> [www.maine.cite.org/glossary.html](http://www.maine.cite.org/glossary.html).

<sup>viii</sup> [http://www.ilcwr.org/PDF\\_files/disabilities\\_universal\\_design.pdf](http://www.ilcwr.org/PDF_files/disabilities_universal_design.pdf).

<sup>ix</sup> Helen Osborne, Communicating With Patients Who Are Visually Impaired, On Call (Oct. 2000).

<sup>x</sup> See, Endnote v supra.

<sup>xi</sup> Frederick K. Schroeder, Ph.D., Commissioner, Braille: A Revolution, US Rehabilitation Services Administration, US Dept. of Education.

<sup>xii</sup> See, [www.dynamic-living.com](http://www.dynamic-living.com).

<sup>xiii</sup> See, Endnote v supra. .