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PHARMACY PRACTICE: A REPORT ON PHARMACISTS' USE OF PRINTED PACKAGE INSERTS

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Author:

Sarah Butler Vice President, NERA

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Sarah Butler is a Vice President at NERA and is part of the Intellectual Property, Product Liability, Antitrust, and Labor Practices where she conducts survey research, market analysis, and sampling analysis on a wide range of topics regarding business and consumer decision making, consumer choice, and consumer behavior. She has conducted numerous studies for leading corporations and government agencies. She is a member of the American Association of Public Opinion Research and the American Statistical Society.

NERA Economic Consulting
4 Embarcadero Center, Suite 400
San Francisco, California 94111-4156
Tel: 1 (415) 291-1050 Fax: 1 (415) 291-1020
www.nera.com

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Executive Summary

NERA Economic Consulting ("NERA") designed and conducted research to assist Arnold and Porter with its investigation of pharmacists' awareness of and preference for electronic labeling or printed package inserts. Specifically, this research addresses how and to what extent pharmacists use the printed package inserts, how printed package inserts help to facilitate the appropriate dispensing of medication, and pharmacists' perceptions of potential exclusive e-labeling schemes.

A national sample of 400 pharmacists across the United States completed this survey. The survey was conducted according to standard research practice.

The survey results demonstrate that the overwhelming majority of pharmacists consult the printed package inserts with regularity, and use the information contained therein to facilitate their practice. Pharmacists are generally not familiar with e-labeling. While they can see some benefit to information provided online, the majority indicates that both printed inserts and e-labeling would be important tools for providing access to critical, clinical information. Even of the pharmacists who prefer e-labeling, over one third indicate that they want printed package inserts to be provided with the product. In other words, of those professionals who indicate they prefer e-labeling, one third still want the ability to consult and rely on printed package inserts as they currently use this information source.

I. Background

In August 3rd, 2013, Office of Information and Regulatory Affairs (OIRA) at OMB received proposed regulation language which, if accepted, would result in the replacement of printed package inserts with mandatory e-labeling. The regulation was entitled "Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products" and it proposed in brief, the following:

> This rule would require electronic package inserts for human drug and biological prescription products with limited exceptions, in lieu of paper, which is currently used. These inserts contain prescribing information intended for healthcare practitioners. This would ensure that the information accompanying the product is the most up-to-date information regarding important safety and efficacy issues about these products. [1]

The proposed rule does not provide for e-labeling in addition to the professional package inserts, but instead requires the ultimate elimination of printed packaging inserts used by professionals. The rule does not affect the inserts provided to patients with prescriptions.

A number of parties responded to the proposed regulation; including, The National Community Pharmacists Association,[2] the Biotechnology Industry Organization,[3] and others. In July 2013, the Government Accounting Office (GAO) undertook a congressionally mandated study to evaluate the potential advantages and disadvantages of the complete substitution of printed package inserts with electronic labeling.

The GAO interviewed public health officials (including individuals from the FDA, the National Library of Medicine, and the Agency for Healthcare Research and Quality). The GAO also interviewed individuals from stakeholder organizations—including drug manufacturers, printed literature manufacturers, health care practitioners with prescribing authority, pharmacists and pharmacies, patient advocates, and academic researchers.[4] The GAO found that while there may be advantages to e-labeling, its research also demonstrated that there are significant disadvantages as reported by the stakeholders including; limitations on internet access for professionals relying on the package insert information, unfamiliarity with online sources and

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[1] See, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201304&RIN=0910-AG18 accessed December 22, 2014.

[2] See NCPA April 4, 2014 Letter.

[3] See, "BIO Comments on e-labeling" letter from Andrew J. Emmett to Commissioner Margaret Hamburg and Director Sylvia Matthews Burwell, dated January 22, 2014.

[4] See, GAO Report, *Electronic Drug Labeling: No Consensus on the Advantages and Disadvantages of its Exclusive Use.* July, 2013.

access, and the inability to share online information with patients without an investment in printers and paper.[5]

On December 18, 2014, the proposed rule was officially proposed by the FDA by publication in the Federal Register. In the proposed rule, the FDA indicated that e-labeling would provide, "that the most current prescribing information for prescription drugs will be available and readily accessible to health care professionals at the time of clinical decision making and dispensing."[6] The FDA cites to an analysis to demonstrate that there are potentially substantial savings for the pharmaceutical industry and are some potential costs to pharmacies. The FDA indicates the net savings (savings to manufacturers minus costs to pharmacies) ranges between approximately 5 and 82 million over the next ten years.[7] While the analysis cited by the FDA attempts to incorporate the practices of pharmacists and includes an assessment of costs associated with printed information, the report relied upon by the FDA does not evaluate healthcare professionals' preferences and attitudes towards e-labeling nor does it specifically quantify the proposed public health benefits.[8,9]

The NERA research examines how pharmacists use the printed package inserts for professionals and further investigates the extent to which pharmacists view the inserts as an important source of information. In addition, this research examines whether pharmacists, in their current practice, rely on printed package inserts for essential prescribing information. Finally the research evaluates pharmacists' preferences for printed package inserts, e-labeling, or both as professional resources.

II. Research Methodology

NERA's research follows the generally accepted principles for the design of a reliable and rigorous survey. To ensure that a survey yields valid data careful attention must be paid to the following key areas:

- The definition of the relevant population;
- The procedures for sampling from the relevant population;

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[5] *ibid*, p. 10-13.

[6] See, https://www.federalregister.gov/articles/2014/12/18/2014-29522/electronic-distribution-of-prescribing-information-for-human-prescription-drugs-including-biological#page-75509 accessed December 22, 2014.

[7] *ibid*, p. 75507.

[8] See, *Electronic Distribution of Labeling Proposed Rule: Final Report Economic Impact Analysis Task Order*, dated October 4, 2010. NERA has not undertaken an examination of the costs reported in the proposed rule.

[9] In a prior ruling on labeling, the FDA provided a general, "uncertain" cost benefit analysis which included both time savings to health care practitioners and adverse events avoided. A similar analysis of time savings and impact on adverse events was not conducted for the recent proposal. (See, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Product*, dated January 24, 2006. Federal Register Volume 71, No. 15. p. 3969)

- The survey questions used;
- The nature of the specific stimuli shown to respondents; and,
- The protocol for calculating the results from the survey.[10]

The following discussion is organized around these key areas.

1.1. Definition of the Relevant Population

While some physicians, nurses, and EMT use professional printed package inserts (hereafter "professional PI"), pharmacists are the primary group of health care professionals referencing the drug information provided by professional PIs. Therefore, for the purpose of this study the relevant population consists of all licensed pharmacists currently working in the United States. According to the Bureau of Labor statistics there were 286,400 employed pharmacists in the U.S. in 2012.[11]

1.2. Sampling of the Relevant Population

To sample from the relevant population, potential respondents were contacted through an online survey panel of health care professionals who agree to participate in research. The survey panel was supplied by M3 Global Research, a renowned provider of qualified medical professional survey respondents. M3 is a member of CASRO (Council of American Survey Research Organizations), ESOMAR (World Association for Opinion and Marketing Research) and is a verified member of the Marketing Research Association (MRA).

To qualify for the survey, respondents had to indicate that they were currently employed as a pharmacist and that their primary employment was not working in; a mail-order pharmacy, home health, pharmacy benefits administration or an academic institution.

To ensure that the survey population was representative of the relevant population, NERA instructed the survey panel company to set quotas that reflected the U.S. pharmacist population in terms of geography. Table 1 provides the geographic distribution of survey respondents relative to the distribution of U.S. pharmacists and the population of the United States.

[10] *Manual for Complex Litigation*, Fourth Edition. p. 103 (11.493). Federal Judicial Center, 2004.

[11] See http://www.bls.gov/ooh/healthcare/pharmacists.htm#tab-1 accessed December 5, 2014.

Table 1: Geographic Distribution of Pharmacists

State	NERA Survey Respondents (n = 400)	2009 National Pharmacist Workforce Survey Respondents[1] (n = 1,391)	General State Population as a Percent of Total US Population[2] (n = 318,857,056)
AL	1.50%	1.94%	1.52%
AK	0.25%	0.07%	0.23%
AZ	1.50%	1.80%	2.11%
AR	1.00%	1.01%	0.93%
CA	5.00%	7.40%	12.17%
CO	1.50%	1.94%	1.68%
CT	0.75%	1.58%	1.13%
DE	0.25%	0.36%	0.29%
DC	0.00%	0.00%	0.21%
FL	4.00%	5.46%	6.24%
GA	4.00%	2.88%	3.17%
HI	0.25%	0.14%	0.45%
ID	0.25%	0.36%	0.51%
IL	4.50%	6.04%	4.04%
IN	0.75%	2.59%	2.07%
IA	2.25%	1.73%	0.97%
KS	0.75%	1.44%	0.91%
KY	1.50%	2.30%	1.38%
LA	2.25%	1.08%	1.46%
ME	1.00%	0.36%	0.42%
MD	2.25%	2.30%	1.87%
MA	1.25%	2.52%	2.12%
MI	1.75%	3.59%	3.11%
MN	1.00%	2.44%	1.71%
MS	0.75%	0.72%	0.94%
MO	2.75%	1.87%	1.90%
MT	0.75%	0.65%	0.32%
NE	0.75%	0.79%	0.59%
NV	0.75%	0.58%	0.89%
NH	0.00%	0.36%	0.42%
NJ	6.00%	3.45%	2.80%
NM	0.00%	0.36%	0.65%
NY	14.75%	5.10%	6.19%
NC	6.25%	2.95%	3.12%
ND	1.25%	0.29%	0.23%
OH	3.75%	4.67%	3.64%
OK	0.00%	1.08%	1.22%
OR	0.75%	1.29%	1.25%
PA	6.50%	5.46%	4.01%
RI	0.25%	0.14%	0.33%
SC	2.00%	1.58%	1.52%
SD	0.75%	0.29%	0.27%
TN	2.75%	2.88%	2.05%
TX	2.50%	5.46%	8.45%
UT	0.75%	0.64%	0.92%
VT	0.00%	0.14%	0.20%
VA	1.00%	2.66%	2.61%
WA	1.50%	2.08%	2.21%
WV	1.25%	0.86%	0.58%
WI	2.25%	2.01%	1.81%
WY	0.50%	0.29%	0.18%

[1] *Source: http://www.aacp.org/resources/research/pharmacyworkforcecenter/Documents/2009%20National%20Pharmacist%20Workforce%20Survey%20-%20FINAL%20REPORT.pdf accessed January 20, 2015.*

[2] *Source: http://www.census.gov/popest/data/national/totals/2014/index.html accessed January 20, 2015.*

NERA also instructed M3 to ensure that sufficient numbers of survey respondents were working in independent pharmacies or pharmacies with fewer than ten stores under the same ownership. Table 2 below provides the distribution of workplace type for the survey respondents.

Table 2: Pharmacists' Place of Work

Place of Work	Percent of Survey Respondents
Independent Community Pharmacy (fewer than 4 stores under the same ownership)	29%
Large Chain Community Pharmacy (more than 10 units under same ownership)	22%
Non-government Hospital / Health System	20%
Supermarket Pharmacy	8%
Small Chain Community Pharmacy (4 to 10 stores under the same ownership)	7%
Mass Merchandiser (i.e. Big Box store)	5%
Clinic-Based Pharmacy	5%
Government Hospital / Health System	4%
Nursing Home / Long Term Care	2%
Total	400

1.3. Survey Questions and Procedures

Potential respondents were sent an email invitation to participate in the study by the panel vendor.[12] Respondents began the study by completing the screening questions described above.

The main questionnaire began by indicating to respondents that the survey was about materials that they may or may not use to do their jobs. Respondents were also told that their honest opinions were desired and if they did not know an answer to a question, or had no opinion, they could indicate this and should not guess.

Qualified pharmacists were asked about internet access at their workplace and were then provided with a list of information sources they may or may not use, including the printed package insert. Those who indicated they use the printed package insert were asked to describe

[12] As is standard practice, the study was double blind, neither the panel vendor nor the respondents knew the purpose of the study or sponsor of the study.

how the professional PI is used and were also asked to identify, from a list, types of information the professional PI provides. Respondents were then asked how recently and how frequently they use the professional PI.

All respondents (regardless of whether or not they used the printed package insert) were asked whether or not they were aware of e-labeling; that is, providing the drug information that is normally contained on the printed package insert, electronically.

Regardless of their awareness of e-labeling, pharmacists were asked to evaluate a number of statements and were asked to indicate whether printed package inserts are better, e-labeling is better, or both printed inserts and e-labeling are equally important. To ensure that this series of questions did not create bias by suggesting to respondents one method was preferable, the type of information source shown first ("printed packaging better" or "e-labeling better") was randomized such that half of all respondents saw one source first and the remainder saw the other source first.

Finally, respondents were asked to indicate which information source they preferred. Those who indicated e-labels were preferable were asked an additional series of questions. Pharmacists preferring e-labels were asked whether they thought printed package inserts should be eliminated or should remain available, and if so, to what extent.

At the completion of the survey, respondents were thanked for their time and participation. A total of 400 pharmacists completed the survey.

III. SURVEY RESULTS

1.1. Internet Connectivity

While the majority of pharmacists have internet access, a sizable proportion has limited or no internet access at all at their place of work. A total of 27 percent of the pharmacists surveyed (107 respondents)[13] indicate that their pharmacy either does not have internet access or that they cannot browse the internet.[14] Of the pharmacists that do have internet access at their place of work, the overwhelming majority, 82 percent of respondents with access, have experienced a loss in internet connectivity (for example, due to a storm or power outage).

1.2. Use of the Professional Printed Package Insert

[13] This includes four respondents who don't know if they have internet or if they can browse online.

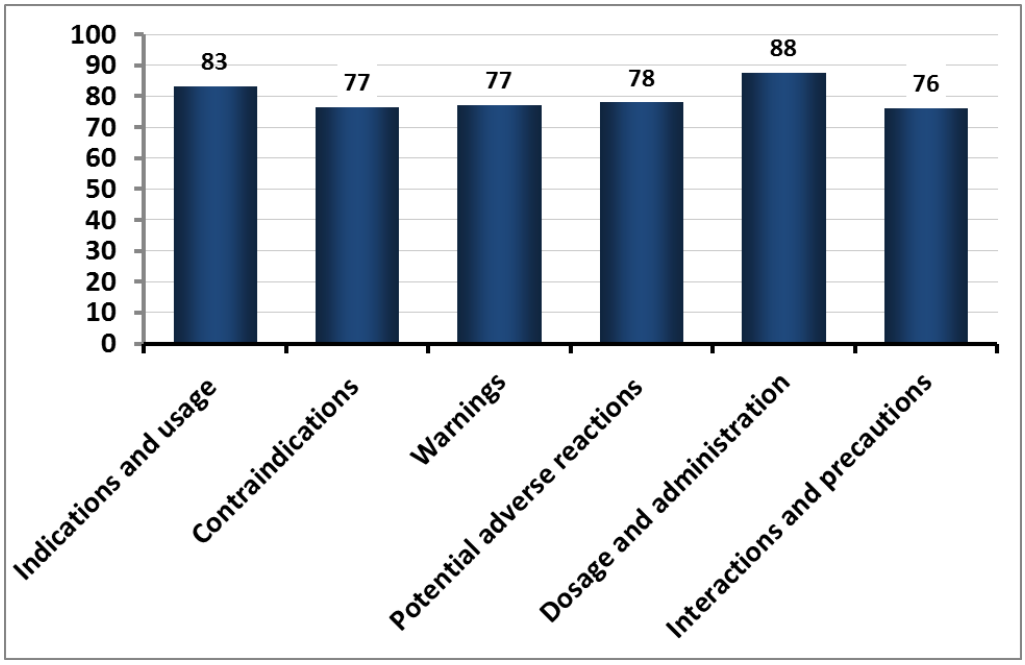
[14] Pharmacies that do not have browsing capabilities are those which likely only use internet connections for billing and invoicing. Some pharmacies have restrictions on internet accessibility due to privacy concerns.

The overwhelming majority of pharmacists surveyed indicate that they have used the printed package insert for professionals; 88 percent of respondents indicate that they have used the professional PI as an information source when filling or dispensing a prescription. More than half of the respondents (55 percent) also indicate they have provided the professional PI to patients.

When asked to describe how they use the professional PI, pharmacists indicate that they use this information to help in counseling patients, to look for inactive ingredients (in case of allergic reactions), to evaluate safety of drug for different types of patients (for example, pregnant women), and to determine whether a drug can be safely split or crushed. Pharmacists also indicate that they use the professional PI for a "quick" or easily accessed source of information or as a means to check dosing. A few respondents indicate that the professional PI is an alternative to insufficient online information or is preferable to trying to retrieve information using a slow internet connection.

When asked about specific types of use, pharmacists indicate that they utilize the professional PI in a variety of important ways. As shown below in Figure 1, pharmacists use professional PIs for a variety of type of dosing and prescribing information. For example, 88 percent of pharmacists surveyed have used the professional PI for information about drug dosage and administration and 83 percent have used the professional PI for information about drug indications and usage.

Figure 1: Percent of Pharmacists Who Have Used Professional PI for….



Not only does the professional PI provide essential drug information to pharmacists, but the professionals surveyed review the professional PI regularly. The majority of pharmacists

surveyed indicate that they have checked information provided by the professional PI within the most recent week. Moreover, as shown below in Table 3, more than 80 percent of those who use the professional PI have checked it within the last month.

Table 3: Most Recent Reference to PPI

Response	Percent of Respondents Who Use PPI	Percent of ALL Respondents
In the last week or more recently	54.9%	49.3%
In the last few weeks to a month ago	28.1%	25.3%
More than a month ago	17.0%	15.3%
Do not consult/ don't know	--	10.3%
Total	**359**	**400**

Table 4 below demonstrates that pharmacists regularly consult the professional PI for a variety of different types of information. Approximately half of the respondents look at least monthly to the printed package insert for indications and usage information, drug contraindications, drug warnings, potential adverse reactions, dosage and administration and interactions and precaution information.

Table 4: Frequency of Use by Type of Information

Type of Information	Use often (weekly)	Use Somewhat (monthly)	Use infrequently (few times a year)	Use rarely (once a year or less)	Don't Use / No Opinion
Indications/usage	17.6%	39.8%	27.2%	11.8%	3.6%
Contraindications	14.0%	36.5%	26.6%	16.2%	6.6%
Warnings	13.2%	35.7%	30.2%	13.7%	7.1%
Adverse reactions	16.8%	37.9%	26.9%	11.5%	6.9%
Dosage/administration	22.8%	42.6%	25.0%	6.9%	2.7%
Interactions/precautions	15.4%	38.2%	26.9%	11.0%	8.5%

On average, each pharmacist who consults the professional PI on at least a weekly basis is dispensing 155 prescriptions per day. This estimate is similar to the findings in the FDA's 2006

rule that there are approximately 12 printed labeling consultations by retail pharmacists for every 1,000 prescriptions dispensed.[15]

Questions about how respondents use the professional PI demonstrate that the overwhelming majority of pharmacists have consulted the professional PI recently (within the last month) and that these pharmacists use the package inserts for a variety of important prescribing information. Additionally, hundreds of prescriptions are dispensed on a daily basis by pharmacists who use the professional PI on a regular (weekly) basis.

1.3. E-Labeling

While the majority of pharmacists use the professional PI with regularity, almost three quarters (73.5 percent) of the professionals surveyed have not heard of any exclusive e-labeling initiative for package inserts.[16]

When asked to evaluate a series of statements and to indicate whether printed package inserts are better for their practice, e-labeling is better for their practice or both formats would be important to their practice, the majority of pharmacists indicate that both information sources are important. As shown below in Table 5, almost half of all pharmacists indicate that printed packages inserts are better or professional PIs and e-labeling are equally important for their practice. More importantly, less than twenty percent of respondents believe that e-labeling is better at providing "trustworthy" information and only 25 percent of respondents believe that e-labeling would be better at providing accurate information. Table 5 also demonstrates that approximately 20 percent of respondents didn't have an opinion for a number of the statements and this is likely due in part, to pharmacists' unfamiliarity with e-labeling and what it might mean for their practice.

[15] *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Product*, dated January 24, 2006. Federal Register Volume 71, No. 15. p. 3972.

[16] This includes a small number of pharmacists who say they don't know if they have heard of e-labeling (11 respondents) or have no opinion (3 respondents).

Table 5: Comparison of PPI and E-labeling for Pharmacists' Practices

Statement	Printed Package Insert is Better	Both PPI and E-labeling are Important	E-Labeling is Better	Don't Know/ No Opinion
Information Can Easily Be Provided to Patient	25.00%	27.50%	25.00%	22.50%
Information is Immediately Accessible	20.50%	26.75%	35.25%	17.50%
Information is Always Available	18.00%	30.25%	35.50%	16.25%
Easy to Use	16.75%	25.25%	36.75%	21.25%
Provides Current Drug Information	10.00%	37.25%	33.75%	19.00%
Provides Accurate Information	9.75%	44.50%	25.00%	20.75%
Information is Trustworthy	8.75%	53.00%	18.50%	19.75%
Better for the Environment	4.25%	11.75%	70.00%	14.00%

Pharmacists were also asked to assess their overall attitude towards professional PIs and e-labeling. When asked the following question:

> **Q.** Which of the following statements best represents your opinion?
>
> 1. I prefer printed package inserts to e-labeling
> 2. Printed package inserts and e-labeling are about the same
> 3. I prefer e-labeling to printed package inserts
> 4. Don't know/no opinion

the majority of pharmacists (52.3 percent) indicate that they either preferred professional PIs or indicate that professional PI and e-labeling are about the same.

Those who indicated that they prefer e-labeling were then asked whether they thought professional PIs should be available as they are now, should only available on request or should be eliminated entirely. Of the 128 pharmacists who indicated that they prefer e-labeling, more than one third, 37 percent, would want to continue to have professional PIs provided as they are now. In other words, of the 400 pharmacists studied, 80 percent view professional PI as a source of information equal to e-labeling or believe that professional PI should remain available as they are now in addition to e-labeling.

IV. PUBLIC HEALTH IMPLICATIONS OF THE PROPOSED RULE

A number of parties, including the FDA, have made claims related to the purported benefits of the proposed rule. While the recent FDA publication emphasizes the cost saving and benefits for

manufacturers and pharmacies,[17] the FDA has also argued that the proposed rule would provide pharmacists with the most up-to-date drug information, thereby benefitting public health. As stated in the rule, "FDA is taking this action to ensure that the most current prescribing information for prescription drugs will be available and readily accessible to health care professionals at the time of clinical decision making and dispensing."[18] Similar benefit claims have been made by those representing the drug manufacturing industry.[19] The alleged benefits to public health that the FDA and other parties argue will be brought about by the proposed rule are reviewed below.

The FDA and others assert that the key public health benefit from e-labeling is the provision of up-to-date information for health care practitioners, including pharmacists. For pharmacists to be able to utilize this benefit (and therefore better serve patients) a number of conditions must be met. For exclusive e-labeling to bring about public health benefits, pharmacists must: 1) have both a computer and internet access; 2) have a reliable internet connection; 3) trust and be comfortable with the online access; and 4) believe that exclusive e-labeling allows them to better consult with and provide information to their patients. Yet, data collected from the NERA study, as well as another study (discussed below), suggest that many of these conditions are not met for pharmacists. Therefore, these data suggest that the alleged health benefits of exclusive e-labeling are unproven and in fact, exclusive e-labeling is contrary to the wants and current practice habits of the majority of pharmacists in the United States.

1.4. Internet Access

The NERA study demonstrates that the while the majority of pharmacists have internet access, a substantial proportion do not or cannot browse the internet. These results are confirmed by the results of other studies, notably the study conducted by academic researchers Yun-Xian Ho, Qingxia Chen, Hui Nian, and Kevin B Johnson from Vanderbilt University.[20] This study, entitled, "An assessment of pharmacists' readiness for paperless labeling: a national survey" was cited by an organization representing the biotechnology industry to the FDA in support of its position advocating e-labeling.[21] But, in fact, many findings from this study support the results of the NERA study and the results from this study do not indicate that pharmacists prefer exclusive e-labeling.

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[17] See, https://www.federalregister.gov/articles/2014/12/18/2014-29522/electronic-distribution-of-prescribing-information-for-human-prescription-drugs-including-biological#page-75509 accessed December 22, 2014. p. 75507.

[18] *ibid*, p. 75507.

[19] "Paperless labeling will improve patient safety as health care providers (HCPs) will have access to the most recent FDA-approved US Prescribing Information (USPI), detailing a medicine's safety, efficacy, and conditions of use, in a format that can be updated in a matter of days rather than weeks or months." in "BIO Comments on e-labeling" letter from Andrew J. Emmett to Commissioner Margaret Hamburg and Director Sylvia Matthews Burwell, dated January 22, 2014. p. 2.

[20] Ho Y-X, et al. (2014) "An Assessment of Pharmacists' Readiness for Paperless Labeling: a National Survey" in *Journal of American Medical Information Association;* Volume 21.

[21] See, "BIO Comments on e-labeling" letter from Andrew J. Emmett to Commissioner Margaret Hamburg and Director Sylvia Matthews Burwell, dated January 22, 2014. p. 4.

For example, the Ho study demonstrates that while most pharmacies have computers and the internet, some number of pharmacists are limited in their ability to search and access information online. Indeed, the Ho study provides specific examples of pharmacists who are concerned that e-labeling will not be accessible to all professionals due to corporate restrictions on internet access, or because some pharmacies are without internet connectivity.[22]

Additionally, as both the NERA study and the Ho study show, internet access can be unreliable. In the NERA study, a total of 82 percent of respondents have experienced a loss of internet connectivity and some respondents in the Ho study (as well as those in the NERA study) indicate that slow and unreliable connections can make internet access an undesirable means for accessing prescribing information. For example, the Ho study reports:

> Nonetheless, some pharmacists also raised concerns about delays in the process due to technical limitations noting, 'I (sic) may delay information, due to slow computers!' In fact, one pharmacist believed that it is actually 'hard to get exactly the information you need' and it is 'faster to skim a book'.[23]

In the NERA study, some respondents indicate that a slow or unreliable internet connection would be a concern if there was exclusive e-labeling. For example respondents state:

> Faster alternative for drug information than the slow computer/internet system we have access to. Internet access is not always available, reliable, or convenient (slow connection, hard to navigate company intranet). (ID 5198829)
>
> Often I don't have time to run to a computer to search for a topic. Also, if the Internet connection is slow, it takes too long. (sic) at our hospital the technicians do not currently have Internet access--only the pharmacists. (ID 3069799)
>
> There are times when it is faster to use the computer, but there are times when the computer is slower and it is faster to use a printed version. (ID 390624)
>
> Sometimes the pharmacy's internet connection does not work or is working slowly. When you are trying to work in a fast-paced environment the ability to quickly grab the insert off the bottle can save time. It can take more time to switch screens and wait for the info to pull up on the computer, (sic) If I do that then I use Facts & Comparisons (ID 3234447)
>
> internet unreliable (ID 4942890)

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[22] See, Ho Y-X, et al. (2014) p. 47.

[23] *ibid*, p. 46.

> Our internet service is not dependable (ID 3074845)
>
> Don't always have internet capabilities at work (ID 3321271)
>
> always available , internet or site can be down (ID 3150043)
>
> internet not always available. (ID 3169582)
>
> It may be fastest to use e labeling, but what if computer is down or the internet is not working. (ID 3150726)
>
> Lots of pharmacies don't have access to the internet, might be hard to access e-label (ID 4937249)
>
> E labeling sounds great, but if the computers/internet go down, then no info is avail (ID 3234679)
>
> Printed inserts are readily available. Elabels can be a problem to access if internet goes down. (ID 4558555)

Both the NERA and Ho studies are focused on pharmacists in traditional working environments and therefore are somewhat limited in their ability to assess the implications of e-labeling for pharmacists working in non-traditional environments. While both studies include respondents who indicate their pharmacy does not have internet access, both also rely on online data collection methods and therefore may be underrepresenting the extent to which limited access to the internet would impact particular communities (such as active military stationed in remote locations, or pharmacies located in rural or other underserved communities with lower rates of connectivity).

1.5. Current Practice

Multiple studies confirm the findings that pharmacists rely on the professional PI for essential clinical information and also share this information with patients. The NERA study found that the overwhelming majority of pharmacists (88 percent) have used the professional PI and more than half have provided the printed insert to a patient (55 percent). The Ho study reports 92 percent of pharmacists using prescribing information, and 81 percent use this information when counseling patients.[24] Pharmacists' current use of and reliance on the information in the package insert is similar to usage patterns found in studies cited by the FDA in 2006.[25] In this rule, the FDA asserted that the average pharmacist seeks information from the paper drug labeling "257

[24] See, Ho Y-X, et al. (2014), p. 45.

[25] *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Product*, dated January 24, 2006. Federal Register Volume 71, No. 15.

times each year".[26] A number of references in this document indicate the importance of drug information supplied in the professional PI. The benefits of the January, 2006 labeling rule were stated as: Decreased Health Care Practitioner Time, Improved Effectiveness of Treatment, and Decrease in costs to Treat Avoidable Adverse Reactions, collectively resulting in potential benefits of hundreds of millions of dollars in annual savings to the United States health care system.[27] The continued importance of printed package inserts over time suggests that reliance on this information source is an important part of a pharmacist's clinical practice.

1.6. Perceptions of E-Labeling

The NERA data contradicts assertions that exclusive e-labeling would provide the most up-to-date and trustworthy drug labeling information, at least as far as pharmacists' perceptions of this information. The NERA study demonstrates that, on most measures, the majority of pharmacists feel both the professional PI and e-labeling are important for their practice. For example, the NERA survey demonstrates that more than half of all pharmacists surveyed feel that printed package inserts or a combination of professional PIs and e-labeling provide the most trustworthy information. In other words, only 19 percent of respondents believe that e-labeling on its own is a better means of providing trustworthy information. Similarly, only 25 percent of respondents believe that e-labeling on its own provides the most accurate information and only 34 percent believe that e-labeling on its own provides the most current drug information.[28] These results demonstrate that pharmacists do not feel that e-labeling, on its own, is a substitute for the accuracy or trustworthiness of the information provided by the professional PIs. The majority of pharmacists across most measures indicate that professional PIs or the combination of professional PIs and e-labeling is best for their practice.

1.7. Reliability, Ease of Access and Patient Counseling with Professional PI

Pharmacists in the NERA study who prefer professional PIs indicate that these inserts are easy and fast to access, are familiar and allow pharmacists to readily search for needed information. Pharmacists also state that familiarity with the professional PIs allow them access information reliably, with minimal interruption to work flow, and without errors.[29] As indicated below, the GAO Report cites the importance of pharmacy workflow to patient safety and positive outcomes:

> Some pharmacists could find it easier, when counseling patients, to take the paper version of the labeling directly from the drug packaging and show it to the patient at the counter rather than searching for the labeling on a computer and then showing the patient the computer monitor or printing the labeling. If pharmacists' work flow is disrupted because they need to print drug labeling for patients, it

[26] *ibid*, p. 3972.

[27] *Ibid*, p. 3972.

[28] See Table 5 of this report.

[29] See for example respondent ID 5191409 who indicates a preference for professional PIs and states, "Ease- lack of access errors".

> could reduce the time available for patient consultations.. Interruptions to pharmacists' workflow have shown to increase the risk of errors made when dispensing a drug.

Fifty-five (55%) of pharmacists in the NERA study have provided the printed professional PI to patients.

Many pharmacists, including those who prefer professional PIs and those who believe professional PIs and e-labeling are both beneficial, indicate that having a printed source of information to provide to patients is important. Some pharmacists also indicate that paper can be shared between staff and other healthcare professionals. For example:

> When in the pharmacy the paper is convenient, can easily show to patient, patient knows that is the official information when they see paper, don't have to print out at my cost, don't have to have tablets to carry around to show other staff or patients, not always convenient to have to flip between an electronic version and the pharmacy dispensing software. (ID 3107308)
>
> Easier to give to patients (ID 5173589)
>
> Easier to use and more user friendly. Don't have to shout at patient from computer (ID 3150896)
>
> Paper is easily shared (ID 3321710)
>
> I like having something in my hand when I go to the IV room and I don't have a computer back there. (ID 3350853)
>
> sometimes it's good to be able to give the patient, sometimes i just need it (sic) fro reference (ID 3068801)
>
> depends on how I need to access information or how to provide it to another healthcare provider. (ID 5368769)
>
> I believe that both are incredibly important resources to use when evaluating a patients risks, interactions, side effects, etc. Having both is a "back up" system and something that you can always provide to a patient, whom may not have internet access. (ID 4696049)

These responses indicate that pharmacists view the ability to access a paper version of drug information is important in assisting both patients and other healthcare professionals.

V. CONCLUSIONS

The NERA survey and other data reviewed here suggest that exclusive e-labeling would not necessarily bring about the benefits to public health asserted by the FDA and others. Internet

access is not available in some pharmacies and access can be slow, unreliable or a less efficient means of accessing information for some pharmacists. The absence of internet or reliable connectivity is likely to render some pharmacists and their patients without reliable information on drugs prescribed if exclusive e-labeling is enforced. A number of pharmacists in the NERA study express reservations about relying solely on information provided online.

Additionally, studies evaluating current pharmacy practice show that pharmacists rely on, are comfortable with, and look to professional PIs frequently. Pharmacists use professional PIs to provide valuable clinical information, as well as provide these inserts directly to patients and others. The majority of pharmacists surveyed do not feel that exclusive e-labeling provides more trustworthy or current information and the majority of pharmacists see professional PI and e-labeling as equal. Even pharmacists who see e-labeling as a better means of providing information generally prefer to have both online information and the professional PI available as they are now.

The NERA study and this review demonstrates that the overwhelming majority of practicing pharmacists serving patients in the United States utilize professional PI as an important resource to access critical clinical information regarding drug indications, contraindications, drug warnings, adverse reactions, dosage, and drug interactions.

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NERA
ECONOMIC CONSULTING

NERA Economic Consulting
4 Embarcadero Center, Suite 400
San Francisco, California 94111-4156
Tel: 1 (415) 291-1050 Fax: 1 (415) 291-1020
www.nera.com