

# COMMUNITY PHARMACISTS' CLASSIFICATION OF PRESCRIPTION DRUGS INTO DISPENSING

## CATEGORIES UNDER THE FDA'S PROPOSED "NEW PARADIGM"

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### BACKGROUND

- Limited access to prescription medications due to the time and cost associated with a physician visit and safety issues associated with prescription-to-over-the-counter (Rx-to-OTC) switches continues to be a cause for concern.
- Consequently, the FDA has considered creating a third class of drugs which would not require a prescription, but require a pharmacist's consultation upon purchase.
- Recently the FDA held a hearing entitled "Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription"<sup>1</sup>.
- This hearing repositioned a third class of drugs "as a 'new paradigm' under which certain drugs, that would otherwise require a prescription, would be approved for nonprescription use . . . under conditions of safe use"<sup>1</sup>.
- These conditions of safe use would be specific to the drug product and might require sale in certain pre-defined health care settings, such as a pharmacy<sup>1</sup>.
- In order for such a system of patient-directed self-care to work efficiently, the FDA would set up kiosks at pharmacies, computer algorithms or questionnaires on the Internet, which would help the patient to self-diagnose correctly.
- Alternatively, pharmacists could recommend the appropriate drug based on the patient's medical records and inform the patient about the conditions for the safe use of the drug<sup>1</sup>.
- Several aspects of the 'new paradigm' such as establishing conditions for safe use and using innovative technologies appear novel approaches to addressing a third class of drugs<sup>2</sup>.

### STUDY OBJECTIVES

- To determine which drugs community pharmacists believe are acceptable additions to an expanded definition of nonprescription drugs under the 'new paradigm'.

### METHODS

- This cross-sectional study was conducted by means of a self-administered web-based survey which was distributed to a national convenience sample of community pharmacists.
- The survey contained a list of 24 current 'prescription-only' drugs which may be potential candidates for the 'new paradigm', based on criteria outlined by the FDA, and questions related to respondent demographic and practice characteristics.
- Respondents were asked to indicate whether a particular drug should be marketed as a prescription drug, nonprescription drug or as a 'new paradigm' drug.
- Dispensed as prescription only means:** A prescription is required before the pharmacist may dispense the medication.
- Dispensed as a new paradigm medication means:** A medication dispensed under the expanded nonprescription drug class which would require a confirmation of diagnosis by the pharmacist.
- Sold as nonprescription only means:** The patient may purchase the medication over-the-counter without pharmacist intervention.

### RESULTS

TABLE 1: Respondent Classification of Drugs into Dispensing Categories

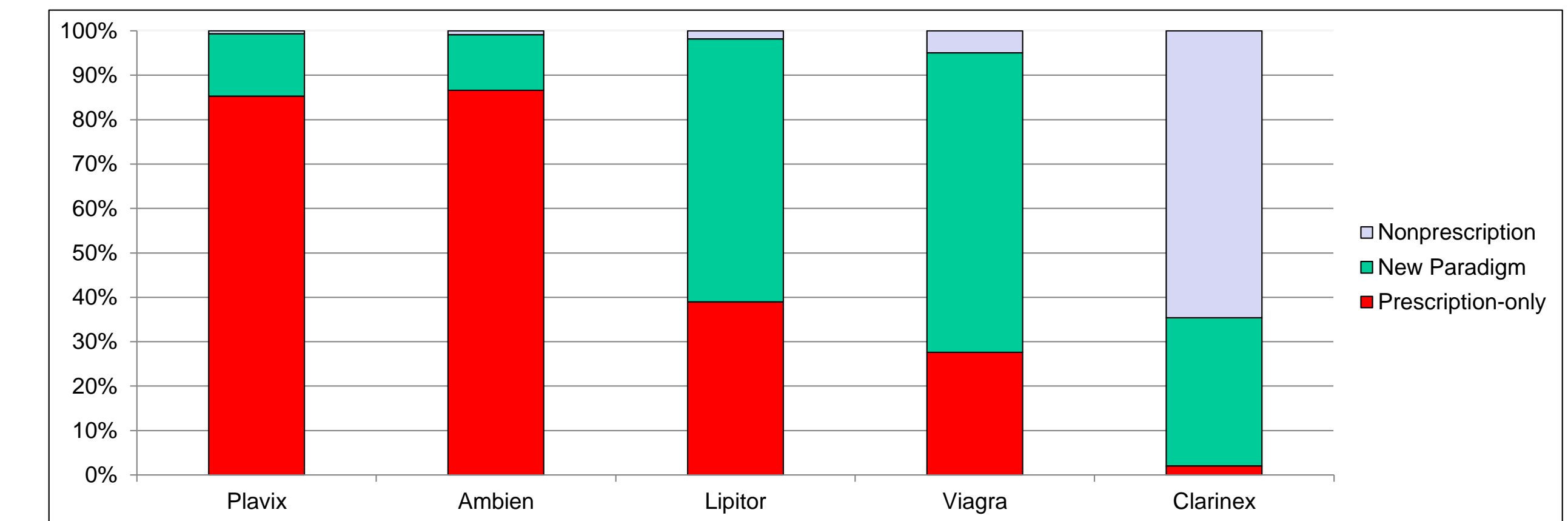
Drug Name <sup>0</sup>	Category under which the Drug should be Dispensed						Total	
	Dispensed as Prescription Only		Dispensed as a "New Paradigm" Medication		Sold as Nonprescription Only		N	%
	N	%	N	%	N	%	N	%
atorvastatin	175	39.0	266	59.2	8	1.8	449	100
metformin	201	44.8	242	53.9	6	1.3	449	100
clopidogrel bisulfate	383	85.3	63	14.0	3	0.7	449	100
hydrochlorothiazide	106	23.6	316	70.4	27	6.0	449	100
lisinopril	152	33.9	288	64.1	9	2.0	449	100
sildenafil	122	27.2	298	66.5	22	6.3	448	100
finasteride	154	34.4	259	57.8	35	7.8	448	100
valacyclovir hydrochloride	142	31.7	279	62.3	27	6.0	448	100
zolpidem	388	86.6	56	12.5	4	0.9	448	100
clindamycin benzoyl peroxide	22	4.9	277	61.8	149	33.3	448	100
bupropion SR	210	47.0	221	49.4	16	3.6	447	100
Prescription pre-natal vitamins	18	4.0	205	45.8	225	50.2	448	100
eflornithine	101	22.5	231	51.6	116	25.9	448	100
montelukast sodium	159	35.7	248	55.6	39	8.7	446	100
albuterol	97	21.7	315	70.6	34	7.6	446	100
desloratadine	9	2.0	149	33.4	288	64.6	446	100
fluticasone	42	9.4	298	66.8	106	23.8	446	100
oseltamivir	177	39.7	255	57.2	14	3.1	446	100
betamethasone	110	24.7	287	64.3	49	3.1	446	100
methyl prednisolone	243	54.5	199	44.6	4	0.9	446	100
ondansetron	149	33.4	271	60.8	26	5.8	446	100
sumatriptan	278	62.3	160	35.9	8	1.8	446	100
epinephrine	117	26.2	288	64.6	41	9.2	446	100
promethazine	124	27.8	276	61.9	46	10.3	446	100

Poster presented at the APhA meeting, March 28-31, 2014; Orlando, Florida.

### RESULTS

- Respondents were skeptical about the switching Plavix® and Ambien® to the new paradigm, but affirmative about switching Lipitor® and Viagra® to this proposed class.

FIGURE 1: RESPONDENTS' CLASSIFICATION OF DRUGS INTO DISPENSING CATEGORIES



### CONCLUSIONS

- As the FDA continues to seek feedback from stakeholders, feedback from pharmacists, especially with regard to which medications should be a part of the "new paradigm" class of drugs, is critical.

### STUDY IMPLICATIONS

#### IMPLICATIONS FOR PHARMACY PRACTICE

- The role of the pharmacist in providing patient-directed care would expand, while at the same time potentially reducing physician workload.
- However, the professional liability and time commitments of community pharmacists may also increase.

### REFERENCES

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