ALBURTYLAB

Investigation into the Impact Of Air Pressure Driven Drug Dispensing Machines On the Environment of Pharmacy Workers

Results in Two U.S. Pharmacies

- McKesson/Parata Max

Executive Summary

January 6, 2009

AlburtyLab Project No. SP-2008-02

RELIABLE AEROSOL SCIENCE AND ENGINEERING

INVESTIGATION INTO THE IMPACT OF AIR PRESSURE DRIVEN DRUG DISPENSING MACHINES ON THE ENVIRONMENT OF PHARMACY WORKERS: MCKESSON/PARATA MAX

Executive Summary

This report is an extension of a previous study of the potential negative impact of air pressure driven drug dispensing machines on the environment of pharmacy workers. This study extension addresses the McKesson/Parata Max, an additional air pressure driven dispensing machine recently introduced into the market.

The original study ("Investigation into the Impact of Air Pressure Driven Drug Dispensing Machines on the Environment of Pharmacy Workers, Results in 15 U.S. Pharmacies" published October 15, 2008 www.alburtylab.com) included detailed observation, study and analysis of the McKesson/Parata Robotic Dispensing System (RDS), the ScriptPro Robotic Prescription Dispensing System (SP 200), and the manual counting system, in fifteen pharmacies. The McKesson/Parata RDS is an air pressure driven dispensing machine, while the ScriptPro SP 200 uses a gravity driven process. Manual counting is performed using counting trays and spatulas. The original study determined that the McKesson/Parata RDS was a substantial source of respirable particles, raising concerns of potential exposure of thousands of pharmacy workers. The study further concluded that manual counting was a source of very limited particle emissions and that the SP 200 did not cause any particle emissions.

A core objective of this extension of the original study (Phase III) was to evaluate the McKesson/Parata Max to see if it, like the McKesson/Parata RDS, is a source of significant respirable particle emissions. Like the McKesson/Parata RDS, the McKesson/Parata Max machine uses air pressure to eject pills into prescription bottles www.mckesson.com. The McKesson/Parata Max machine was observed operating in two pharmacies.

As in the original study, this evaluation focused on airborne particles less than 2.5 microns in diameter (PM-2.5). These particles penetrate the lungs deeply and rapidly enter the bloodstream. PM-2.5 particles are believed to cause a number of health problems, including increased heart rate variability and myocardial infarction (heart attacks).

Highly elevated aerosol concentrations of PM-2.5 particles were observed in the workplace areas of pharmacy workers in the vicinity of the operating McKesson/Parata Max machines. For example, maximum PM-2.5 particle concentrations were 1,400% higher than concentrations previously observed and documented in ScriptPro and manual dispensing pharmacies. These elevations were multiples greater than even the 500% elevations previously observed and documented in McKesson/Parata RDS pharmacies. While the McKesson/Parata Max machines were operating, maximum PM-2.5 aerosol mass concentrations increased to levels that were over 1,800% of concentrations observed and documented in ScriptPro and manual dispensing pharmacies. Both of the McKesson/Parata Max pharmacies which were

observed and studied showed substantially higher levels of aerosol concentrations than were observed at any of the pharmacies in the original study, including the McKesson/Parata RDS pharmacies. Table 1 summarizes the results.

As was done in the original study, pharmaceutical residues were identified on reference filters used to sample air near the McKesson/Parata Max machines. A greater number of different aerosol drug residues were identified near these machines than in any of the pharmacies in the original study. Table 2 shows the drugs that were identified. The chemical analyses were limited in scope and there were indications that many other drug agents were present.

Table 1. PM-2.5 Particles in Pharmacy Air Samples

Dispensing Method	Aerosol Particle Concentration		Aerosol Mass Concentration	
	PPL_{Avg}	PPL_{Max}	$\mu g/m^3{}_{Avg}$	$\mu g/m^3{}_{Max}$
Manual	11,601	114,648	1.708	64
ScriptPro SP 200	8,797	105,178	1.705	16
McKesson/Parata RDS	22,903	607,272	2.510	854
McKesson/Parata Max	26,638	1,699,244	4.779	1,193

PPL = Particles per liter of air, used to measure the number of particles in a volume of air.
$\mu g/m^3$ = Micrograms per cubic meter of air, used to measure the weight (mass) of the particles in a volume of air.
Manual, SP 200, and RDS values are from Phase II of the original study.

Table 2. Compounds in Air Samples from McKesson/Parata Max Pharmacies

Compound	Function
Acetaminophen	Analgesic
Atenolol	Anti hypertensive
Baclofen	Muscle relaxer and anti spastic
Benztropine	Anti cholinergic
Butalbital	Barbiturate
Caffeine	Stimulant
Carisoprodol	Muscle relaxer
Clonidine	Anti hypertensive
Dicyclomine	Antispasmodic and anti cholinergic
Enalapril	Anti hypertensive
Hydroxychloroquine	Anti inflammatory
Isosorbide	Vasodilator
Labetalol	Anti hypertensive
Lansoprazole	Proton pump inhibitor
Loratadine	Antihistamine
Metformin	Anti hyperglycemic
Methadone	Opioid
Niacin	Vitamin
Nifedipine	Anti hypertensive
Nitrofurantoin	Antibiotic
Oxybutynin	Antispasmodic
Penicillin	Antibiotic
Phentermine	Amphetamine class appetite suppressant
Propranolol	Anti hypertensive
Pseudoephedrine	Decongestant
Sulfamethoxazole	Antibiotic
Temazepam	Sleep aid
Tramadol	Opioid
Trimethoprim	Antibiotic

AlburtyLab, Inc., working with Inovatia (www.inovatia.com) and the University of Missouri Mass Spectrometry Facility, conducted this study in the two retail pharmacies over 24-hour periods to determine concentration levels, size characteristics, and chemical properties of pill dust generated by the McKesson/Parata Max machines. The observations were conducted over a two month period ending in December 2008.

These results substantiate significant concerns that pharmacy workers are exposed to airborne drug agents when they use air pressure driven drug dispensing robots. It further appears that the McKesson/Parata Max, recently released to the market, has even higher particle emissions

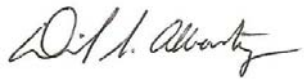
than the McKesson/Parata RDS previously observed and tested as part of the three methods which were subject to the original study.

Recommendation

This study once again points out the need for additional federal review. Serious issues relative to exposure risks for workers in pharmacies using air pressure driven dispensing machines need additional review. Specifically, further studies should be conducted by federal regulatory agencies to assess risk, set guidelines for these types of machines, and establish procedures to monitor the health impact on pharmacy workers.

Mr. David S. Alburty and Mrs. Pam Murowchick of AlburtyLab, Inc. were the principal investigators and authors of this report.

Approved for:
ALBURTYLAB, INC.



David S. Alburty
President
January 6, 2009

About AlburtyLab, Inc.

AlburtyLab is an independent laboratory located in Drexel, Missouri that serves the aerosol research, development, and instrumentation communities. AlburtyLab has conducted independent studies for a range of agencies and companies, including Boeing/U.S. Navy, Boston Scientific, Northrop Grumman, U.S. Postal Service, U.S. Department of Homeland Security, and the U.S. Army Research Laboratory.

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This study was funded by one of the technologies reviewed in the original study, ScriptPro LLC of Mission, Kansas.

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