The following peer-reviewed scientific research papers duplicate Dr. Wakefield's original findings in five additional countries, including the US, Italy, Venezuela, Canada and Poland:

- Gonzalez, L. et al., Endoscopic and Histological Characteristics of the Digestive Mucosa in Autistic Children with gastro-Intestinal Symptoms. Arch Venez Pueric Pediatr. 69:19-25, 2005
- 2. Balzola, F., et al., Panenteric IBD-like disease in a patient with regressive autism shown for the first time by wireless capsule enteroscopy: Another piece in the jig-saw of the gut-brain syndrome? American Journal of Gastroenterology. 100(4):p. 979-981, 2005
- **3.** Balzola F., et al Autistic enterocolitis: confirmation of a new inflammatory bowel disease in an Italian cohort of patients. **Gastroenterology** 128(Suppl.2);A-303, 2005
- **4.** Krigsman A, Boris M, Goldblatt A, Stott C. Clinical presentation and histologic findings at ileocolonoscopy in children with autistic spectrum disorder and chronic gastrointestinal symptoms. **Autism Insights**. 1:1-11, 2009
- 5. Horvath K., Papadimitriou J.C., Rabsztyn A., Drachenberg C., Tildon J.T. Gastrointestinal abnormalities in children with autism. J. Pediatrics 135:559-563, 1999
- **6.** Sabra S, Bellanti JA, Colon AR. Ileal lymphoid hyperplasia, non-specific colitis and pervasive developmental disorder in children. **The Lancet** 352-234-5, 1998
- Sabra A, Hartman D, Zeligs BJ et al., Linkage of ileal-lymphoid-nodular hyperplasia (ILNH), food allergy and CNS developmental abnormalities: evidence for a non-IgE association. Ann Allergy Asthma Immunol, 82:8, 1999
- 8. Galiatsatos P, Gologan A, Lamoureux E, Autistic enterocolitis: Fact or fiction? Can J Gastroenterol, 23:95-98, 2009
- **9.** Jarocka-Cyrta et al. Brief report: eosinophilic esophagitis as a cause of feeding problems in an autistic boy. The first reported case. J. Aut. Dev. Disord. Online July 10, 2010

The following research citations support the findings of Wakefield and colleagues original findings:

- Furlano R, Anthony A, Day R, Brown A, McGarvey L, Thomson M, et al. Colonic CD8 and T cell filtration with epithelial damage in children with autism. J Pediatr 138:366-72, 2001
- Torrente F., Machado N., Perez-Machado M., Furlano R, Thomson M., Davies S., Wakefield AJ, Walker-Smith JA, Murch SH. Enteropathy with T cell infiltration and epithelial IgG deposition in autism. Molecular Psychiatry, 7:375-382, 2002
- **3.** Ashwood P, Murch SH, Anthony A, Hayes C, Machado MP, Torrente F, Thomson MA, Heuschkel R, Wakefield AJ., Mucosal and peripheral blood lymphocyte cytokine profiles in children with regressive autism and gastrointestinal symptoms: Mucosal immune activation and reduced counter regulatory interleukin-10. **Gastroenterol**, 122(Suppl):A617, 2002
- **4.** Ashwood P, Anthony A, Torrente F, Wakefield AJ. Spontaneous mucosal lymphocyte cytokine profiles in children with autism and gastrointestinal symptoms: mucosal immune activation and reduced counter regulatory interleukine-10. J Clin Immuniol, 24(6):664-73, 2004
- Wakefield AJ., Puleston J. Montgomery SM, Anthony A., O'Leary J.J., Murch SH Entero-colonic encephalopathy, autism and opioid receptor ligands. Alimentary Pharmacology & Therapeutics. 16:663-674, 2002
- 6. Wakefield AJ. The Gut-Brain Axis in Childhood developmental Disorders. Journal of Pediatric Gastroenterology and Nutrition. 34:S14-S17, 2002

- Uhlmann V, Martin CM, Sheils O, Pilkington L, Silva I, Killalea A, Murch SH, Wakefield AJ, O'Leary JJ., Potential viral pathogenic mechanism for new variant inflammatory bowel disease. Molecular Pathology. 55:84-90, 2002
- Ashwood P, Anthony A, Pellicer AA, Torrente F, Wakefield AJ. Intestinal lymphocyte populations in children with regressive autism: evidence for extensive mucosal immunopathology. Journal of Clinical Immunology. 23:504-517, 2003
- Torrente F, Anthony A, Heuschkel RB, Thomson MA, Ashwood P, Murch SH. Focal-enhanced gastritis in regressive autism with features distinct from Crohn's and helicobacter pylori gastritis. Am J Gastroenterol. 99:598-605, 2004
- Ashwood P, Wakefield AJ. Immune activation of peripheral blood and mucosal CD3+ lymphocyte cytokine profiles in children with autism and gastrointestinal symptoms. J Neuroimmunol. 173(1-2):126-34, 2006
- Wakefield AJ, Ashwood P, Limb K, Anthony A. The significance of ileo-colonic lymphoid nodular hyperplasia in children with autistic spectrum disorder. Eur J Gastroenterol Hepatol Aug;17(8):827-36, 2005

<u>Peer reviewed research studies that support the importance of recognizing and treating</u> <u>gastrointestinal symptoms in autistic children</u>:

- **12.** Buie T, et al. Evaluation, diagnosis, and treatment of gastrointestinal disorders in individuals with ASDs: **Pediatrics**, Jan;125 Suppl 1:S19-29, 2010
- **13.** Buie T, et al. Evaluation, diagnosis, and treatment of gastrointestinal disorders in individuals with ASDs: a consensus report. . **Pediatrics.** Jan;125 Suppl 1:S1-18, 2010

<u>Peer reviewed research studies providing further support for gastrointestinal disturbances involving</u> <u>the immune system in autism</u>:

- Jyonouchi H., Sun S., Lee H. Proinflammatory and regulatory cytokine production associated with innate and adaptive immune responses in children with autism spectrum disorders and developmental regression. J. Neuroimmunol. 120(102):170-9, 2001
- Jyonouchi H, Geng L, Ruby A, Zimmerman-Bier B. Dysregulated innate immune responses in young children with autism spectrum disorders: Their relationship to gastrointestinal symptoms and dietary intervention. Neuropsychobiology. 28:5177-85, 2005
- **3.** Jyonouchi H, Geng L, Ruby A, Reddy C, Zimmerman-Bier B. Evaluation of an association between gastrointestinal symptoms and cytokine production against common dietary proteins in children with autism spectrum disorders. J Pediatr. 146(5):605-10, 2005
- **4.** Jyonouchi H, Sun S, Itokazu N. Innate immunity associated with inflammatory responses and cytokine production against common dietary proteins in patients with autism spectrum disorder. **Neuropsychobiology.** 46(2):76-84, 2002
- Vojdani A, O'Bryan T, Green JA, McCandless J, Woeller KN, Vojdani E, Nourian AA, Cooper EL. Immune response to dietary proteins, gliadin and cerebellar peptides in children with autism. Nutr Neurosci. 7:151-61, 2004
- Whitley P, Haracopos D, Knivsberg AM, Reichelt KI, Parlar S, Jacobsen J, Seim A, Pedersen L, Schondel M, Shattock P. The ScanBrit randomized, controlled, single-blinded study of gluten-and casein-free dietary intervention for children with autism spectrum disorders. Nutr Neurosci. 13(2):87-100, 2010

- **7.** Knivsberg AM, Reichelt KL, Hoien T, Nodland M. A randomized, controlled study of dietary intervention in autistic syndromes. **Nutr Neurosci.** 5(4):251-61, 2002
- Balzola F, et al. Beneficial behavioral effects of IBD therapy and gluten/casein-free diet in an Italian cohort of patients with autistic enterocolitis followed over one year. Gastroenterology. 4:S1364, 2008
- **9.** Valicenti-McDermott M., McVicar K., Rapin I., et al., Frequency of gastrointestinal symptoms in children with autistic spectrum disorders and association with family history of autoimmune disease. **Developmental and Behavioral Pediatrics.** 27:128-136, 2006
- Chen B, Girgis S, El-Matary W. Childhood autism and eosinophilic colitis. Digestion. 18:127-129, 2010
- **11.** Sandler R, Finegold SM., Bolte ER., et al. Short-term benefit from oral vancomycin treatment of regressive-onset autism. J Child Neurol. 15:429-435, 2000

Peer reviewed published research studies relating vaccines to autoimmune conditions:

February 18, 2015

Senate Committee on Health Care

Dear Senator Monnes Anderson and Members of the Committee

RE: SB-442, In Opposition

The Oregon Chiropractic Association (OCA) strongly opposes SB-442 which would remove the recently established State of Oregon online vaccine educational exemption-voucher system and in so doing removes informed consent/informed choice for Oregon parents. We support safe and effective vaccines hence the OCA is not anti-vaccine but rather pro-informed consent.

The OCA recognizes that all drugs are associated with some risks and adverse reactions. Because vaccines represent a unique category of drugs, primarily given to healthy infants and children, contemporary medical ethics demands that vaccinations must be carried out with the parent's full and informed consent. This necessitates an objective and full disclosure of the known or foreseeable benefits and risks of the vaccine. The way in which childhood vaccines are often promoted and discussed in the medical pediatric setting indicates that such disclosure is not always given. The "risks" of vaccination are often only discussed in the context of the known risks associated with childhood infectious disease if the parent elects not to have their child vaccinated.

Vaccines are known to have side effects including rare but serious adverse reactions causing serious injury and even deaths. Below is a statement from the vaccine adverse events reporting system (VAERS) web page,

Number of Reports VAERS Receives

VAERS receives around 30,000 reports annually, with 13% classified as serious (e.g., associated with disability, hospitalization, life-threatening illness or death) (CDC VAERS Master Search Tool, April 2, 2008). Since 1990, VAERS has received over 200,000 reports, most of which describe mild side effects such as fever. Very rarely, people experience serious adverse events following immunization. By monitoring such events, VAERS helps to identify any important new safety concerns and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks.

Many different types of adverse events occur after vaccination. About 85-90% of the reports describe mild adverse events such as fever, local reactions, and episodes of crying or mild irritability. The remaining reports reflect serious adverse events involving life-threatening conditions, hospitalization, permanent disability, or death, which may or may not have been caused by a vaccine.

To date some 3,937 individuals or family members have now been compensated via the vaccine injury court some **\$2.8 billion** (exhibit submitted) for serious vaccine injuries or deaths, vaccines are not always benign but indeed come with risks, hence the need for parental informed consent/choice. During the 2013 legislative hearings on SB-132 which established the new online vaccine educational voucher system, when asked, public health officials repeatedly testified the proposed legislation would not take away a parent's right to informed consent and could exempt their child. During the February 19, 2013, Senate Committee on Health Care and Human Services, Senator Tim Knopp repeatedly stated concerns that he could not support SB-132 if the religious exemption was removed. Senator Knopp also voiced concerns that if the intent of SB-132 was to remove the religious exemption, this might conflict with Oregon's Constitution. This question again arises with SB-442 as it appears to remove religious exemptions. Public health officials e.g. Ms. Loren Duncan and other officials repeatedly testified that the intent of SB-132 was not to take away the religious exemption and stated parents could exempt their children for any reason (e.g. religious, philosophical) provided they had completed the online educational program to be produced by the Oregon Health Authority (OHA). The OCA did not oppose SB-132 with that understanding. It should interest the committee members the assumption that parents who choose to exempt their children from a vaccine(s) tend to be disadvantaged, uneducated, or poorly educated, relying primarily on the lay press and/or non-evidence-based lay articles found on the internet, are erroneous they have in fact studied the science. According to a survey in Pediatrics, unvaccinated children in the US have a mother who is at least 30 years old, has at least one college degree, and an annual household income is at least \$75,000.

Truth in science matters, continually reports of research misconduct, biased reporting, conflicts of interest, and outright fraudulent activity by pharmaceutical companies who produce the ever growing list of vaccines, bringing into question the accuracy of the vaccine manufacturers claims of safety and efficacy. This current situation further validates the absolute need for informed consent (a.k.a. taking a philosophical exemption). For example Merck & Co., Inc., the pharmaceutical company who produces the MMR (measles, mumps, and rubella) vaccine is currently accused of fraudulently lying about the efficacy of its mumps vaccine for the purpose of continuing to secure governmental contracts worth \$ millions. In 2012, two former Merck virologists, a group of doctors, and direct payers filed two whistleblower law suits in the Pennsylvania federal court. Merck's attorneys were unsuccessful in their attempts to block the case from going to trial with U.S. Federal District Judge C. Darnell Jones II, recently clearing the case for trial. Judge Jones ruled the whistleblowers and direct purchasers produced enough evidence to establish that false statements could have helped give Merck a monopoly. In 2011, Merck agreed to pay a fine of \$950 million related to the illegal promotion of its painkiller Vioxx, which was finally withdrawn from the market in 2004 after studies found the drug increased the risk of heart attacks. Merck pled guilty to having promoted Vioxx as a treatment for rheumatoid arthritis before it had been approved for that use. The settlement also resolved allegations that Merck made false or misleading statements about the drug's heart safety to increase sales. Ghostwritten studies appear to have been relied upon to support Merck's claim that Vioxx was safe and effective. A 2008 editorial published in the Journal of the American Medical Association (JAMA) questioned whether Merck might have deliberately manipulated

dozens of academic documents published in the medical literature in order to promote Vioxx under false pretenses. It has been estimated that more than 60,000 deaths were caused by the drug before being pulled from the market.

More recently senior scientist with the Centers of Disease Control and Prevention (CDC) William W. Thompson, PhD, has apparently also turned whistleblower alleging he and coworkers at the CDC omitted key research data in their study published in 2004 that concluded there was no connection between the MMR vaccine and autism. According to Dr. Thompson the omitted data revealed an almost three fold increased risk for autism in African American males who had received the MMR vaccine before the age of 36 months. Apparently Congressional hearings will soon be scheduled to address the issue of possible research misconduct by a governmental agency (CDC) and whether the MMR vaccine may indeed cause autism. Original research by Dr. Andrew Wakefield gastroenterologist and surgeon formerly of the UK, now living in Austin, Texas and his co-investigators published two well-known peer-reviewed papers reporting their research findings in 1998 in Lancet 351(9103):637-41 and 2000 American Journal of Gastroenterology, 95:2285-2295). It has recently been said that Wakefield "...admits he faked all the data," however Dr. Wakefield and co-investigators stand by their methodology and the results that called for more research into possible environmental triggers causing gastrointestinal disease and developmental regression. It has now been suggested these two papers from the Royal Free Hospital in the UK were withdrawn for political reasons. Dr. Wakefield and co-investigator's original findings have now been duplicated in peer-reviewed papers in five additional countries including the United States, Italy, Venezuela, Canada, and Poland (scientific citations attached). Several other scientific studies now support the importance of recognizing and treating gastrointestinal symptoms in autistic children and the association of gastrointestinal disturbances involving the immune system in autism (citations attached). The hope is the coming Congressional hearings will finally uncover the truth as per vaccines contributing to autism spectrum disorders.

In summary, indigenous to the contemporary bioethical principle of informed consent/choice (philosophical exemption) is the right of the individual or parent to refuse a medical procedure and its inherent risks. Central to informed consent for adults and their perfectly healthy children is the inviolability of a right to autonomy and self-determination. Modern medical bioethics has rejected the notion that we can treat another individual(s) as a means to an end, regardless of how honorable or alluring that end may appear to be. The Nuremberg Code and subsequent Helsinki Declarations clearly reject the moral argument that the creation of benefits for the many (herd immunity by vaccinations) justifies the sacrifice of the few. Considering the well documented corporate malfeasance by vaccine makers such as Merck Co., Inc., combined with the substantial body of scientific evidence of harm from mild skin reactions to lifelong disabilities and even death, Oregon parents must continue to make the final decision for their children.

Respectfully submitted,

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Oregon Chiropractic Association

Member, State of Oregon Health Evidence Review Commission (HERC)

HERC Subcommittee on Evidence-based Guidelines Development and Coverage Guidance

Oregon Board of Chiropractic Examiners, Chiropractic Practice and Utilization Guidelines Advisory Committee