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Review Article

Neglect of the Public Trust Doctrine in Crohn's Disease's Pandemic: An IDI Perspective

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Abstract

The growing incidence of disease has moved the economic focus to therapeutic intervention. Industrialized nations were instructed as to diseases where the body's immune system identified a cell component within an organ system as being alien and obligated the body's host immunity to attack it (autoimmune diseases).

Keywords: Public Trust Document; Mycobacterium avium Subspecies Paratuberculosis; Crohn's Disease; Mediterranean Diet; Acquired Immunity

Introduction

The Public Trust Doctrine is a legal principle that holds that certain natural resources are held in trust by the government for the benefit of the public. The courts have extended its interpretation to include protection of the public welfare. Government's affirmative duty is to protect its assets for the public's benefit.

The United States Department of Agriculture, USDA) is a grantor and grantee of the Public Trust Doctrine and as such is responsible for protecting the land and its products from becoming a means for both disease induction and creation in both animals and humans.

It has been previously argued that not Crohn's disease, but that the zoonotic Crohn's disease pandemic was a tragic happening that should have never occurred had selected government agencies adhered to their responsibilities within the Public Trust [1]. Once it was established that herbivores infected by *Mycobacterium avium* subspecies *paratuberculosis* (MAP) could shed the organism into its milk and that pasteurization did not effectively alter viability, USDA was put into the compromised position, upholding its mission objective to protect and advance agribusiness and addressing possible danger to the public welfare secondary to zoonotic mycobacterial disease. With no ready solution in hand, USDA initiated a five-year program to attain added information, while licensing MAP diagnostic tests that underestimated the detection of infection [2,3]. USDA reduced the meaningfulness of any positive serological identification of MAP infection by not requiring MAP status to be recorded on an animal's health certificate with this limited knowledge. The net consequence of these actions resulted it dissemination of MAP infected animals across state and national boundaries and the secondary widespread adulteration of milk and milk-based foods. Dissemination of MAP infection among milking herds precedes the progressive increase in the cases of Crohn's disease [4]. The long interim between disease creation and disease manifestation removed the immediate element of urgency.

Material and Methos

The Food and Drug Administration (FDA)'s validation of the tumor necrosis factor alfa blocker, adalimumab, was predicated on the drug's ability to induce temporary clinical remissions in 40% of study individuals versus 17% for subjects receiving a placebo [5]. At 56 weeks post-drug therapy termination, 36% remained in remission compared with 12% of individuals receiving the placebo [2]. The drug's target mechanism of action is the disruption of the body's TH1 immune response to antigen challenge. The drug's statistical validation was achieved against a placebo that had zero direct effect of the target mechanism. The tumor necrosis factor alpha blocker, adalimumab, demonstrated a better than two-to-one therapeutic benefit ratio compared to placebo that did not mitigate the fact that drug therapy initially failed in 60% trial subjects (and ultimately in 100%). After nearly two decades, the use of adalimumab has now been superseded by diet as therapy of greatest efficacy.

Coinciding with the near expiration of adalimumab's patent and based on comparable evidence of efficacy, FDA sanctioned the licensing for Crohn's disease, another biologic from the same company. Patentability due to its comparable action on a different point in the TH1 proinflammatory pathway that had been previously targeted by adalimumab. At the time of its validation of additional biologics for Crohn's disease, The Centers for Disease Control and Prevention possessed documentation attesting to the comparative efficiency of plant-based diets versus biologics in Crohn's disease [6-8].

The statement that CD has no cure is valid only if strict adherence is given "evidence-based" efficacy. Rare individual permanent remission had been achieved by strict adherence to a plant-based, Mediterranean-like diet. Individual cases do not constitute "evidenced based" data, but their documentation requires explanation otherwise the governing medical concept is invalidated. The fact that dietary manipulations have proven to be efficacious in general and specifically in individuals who had failed on adalimumab therapy should have obligated FDA to be cautious in sanctioning drugs with comparable mechanism of action, hoping for a different outcome [9-11].

Why a Mediterranean diet achieves superior results to those attained using a biologic has been addressed by the 2015 Hruska Postulate and subsequent publications [6-8]. The Hruska Postulate stated that Crohn's disease is an immune-mediated disease whose immune mechanism is created by MAP infection in the relative absence of host acquired immunity and whose initial disease manifestation is the consequences of MAP antigen/anti-MAP antibody cytotoxic interaction at MAP's sites of attachment within the ileocecum [7]. The Mediterranean diet is postulated mucosal healing by avoiding the MAP-challenge antigens. Nonoccurrence of antigen/antibody cytotoxicity was advanced to explain the rare attainment of permanent remission attained with prolonged adherence to a plant-based diet.

In humans with intact immunity, MAP is a mycobacterial pathogen of low virulence. With MAP infected newborn infection, once full immunological integrity is attained, MAP undergoes extracellular elimination but retains intracellular presence. Insulated from immunological degradation, MAP functions as a template that responds to antigen specific MAP challenges by the elaboration of Th1 cytotoxic cytokines within immunological memory to reintroduction of MAP's antigen array. In Crohn's disease, MAP can neither be detected with special stains nor cultured from disease tissue containing MAP DNA [12]. That the intracellular MAP template can be destroyed is inferred by the achievement of permanent remissions by individuals with Crohn's disease who followed a Mediterranean-style diet over an extended period and the significant diminution of MAP immunological markers in cow #6124.

Johne's disease is a widespread inflammatory disease of the gastrointestinal tract of herbivores due to *Mycobacterium avium* subspecies *paratuberculosis*. It is deemed a disease without effective cure. After the onset of diarrhea, the animal typically dies within a two-to-three-week period. An experiment-in-nature involving a six-year-old Holstein with advanced Johne's disease demonstrates how enhancement of acquired immunity could destroy extra- and intra-cellular MAP [13]. Polymerase chain reaction (PCR) tests of her blood and milk were repeatedly positive for MAP DNA. To ob-

tain more high-titer anti-MAP antibodies, the animal was removed from the University of Florida Dairy Demonstration Herd and transferred to a regulated research facility. There, she received specific nutrition designed by two veterinary nutrition experts whose objective was to enhance cell-mediated immunity. After ten days of diet-based immune support and stress management, her diarrheal stream that previously could hit a wall seven feet away converted to soft stools. After four months she regained over 200 kg. Her MAP ELISA titter dropped to near normal levels. At necropsy, her gastrointestinal tract exhibited no gross evidence characteristic of Johne's disease. Examination of ultimately 34 microscopic slides of her gastrointestinal tract, independently by two pathologists, failed to identify a single mycobacterium. What was present was extensive infiltration of the lamina propria by eosinophils [14].

Acquired immunity is responsible for the immunological governance of mycobacteria. Plant-based and Mediterranean diets, by their composition, are acquired immunity enhancing. That acquired immunity enhancement can destroy intracellular as well as extracellular MAP answers how permanent remissions had been attained in Crohn's disease by adherence to Mediterranean-like diets: intracellular destruction of MAP's immune templates [15]. A rule exists stipulating that any exception to a prevailing concept necessitates a redefinition of that concept. By diminishing antigen challenge from MAP adulterated milk-based products and meats from herbivores and enhancing acquired immunity, short-term therapeutic intervention produced clinical remissions in 92% of individuals who had failed on therapy with biologics [10,16].

MAP adulteration of milk-based products used in the immediate postpartum period is central to creation of the dysfunctional immune process that characterizes Crohn's disease. The failure to mandate a warning label as to the fact that infant formula and powdered milk, if used in the first four months of a newborn's life, possibly constitute a risk factor for their baby later in life developing Crohn's disease further put into question FDA's proper function properly within the Public Trust [15-17]. Theoretically and ethically, every mother should have all information necessary to make an informed decision as to her baby's future nutrition. Globally, food safety is framed within two precautionary doctrines.

The Rio Declaration on Food Safety and The Sanitary and Phytosanitary Measures of the World Trade Organization. Principle 15 of the Rio Declaration states that "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. "Where there are threats of serious of irreversible damage, lack of full knowledge shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." The World Trade Organization Agreement on Sanitary and Phytosanitary Measures' Article 5.7 allows regulatory measures to be enforced "where relevant scientific evidence is insufficient to demonstrate the safety of the product or commodity".

With respect to the United States, the responsibility for U.S. food safety resides with FDA. Its legal authorization to so function resides primarily in three Supreme Court documents: The Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Protection Inspection Act (21m U.S.C. 451 et seq.), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) Being instruments of administrative law, they must identify a food as being adulterated if it bears or contains any deleterious substance, which renders it injurious to health and is not neutralized by its subsequent processing. Products that are adulterated under these laws cannot enter commerce for food consumption.

The failure to properly adhere to the Public Trust may extend beyond government agencies. It has been stated that the future expansion of Crohn's disease's global pandemic can be reduced by doing little more that proper food labeling, providing pregnant women the information necessary to make an informed decision as to her future baby's welfare and advocating breastfeeding for the first four weeks of a baby's life.

Given the estimated five to six million afflicted individuals, the Crohn's disease pandemic is a costly direct drain on national treasuries of industrialized nations. National variable estimates of costs available per Google are:

- United States - $9,000 -$30,000 per individual
- Canada – $3,3 billion annually
- United Kingdom – 1,580 – 10,000 pounds per individual

- Germany - 1,425 euros monthly for all costs,
- France – 10,000-35,000 euros per individual
- Spain and Portugal – 3,000- 6,000 per individual annually
- Italy 6,90- 7,00 per individual
- Denmark 12,900 per individual
- Denmark -12,900 euros per individual
- Netherlands - 1,628 euros per patient per quarter

Not included in these figures are either direct, unreimbursed out-of-pocket expenses to individuals or indirect costs to the individual nations. Indirect loss secondary to disease are usually calculated at 25% of direct medical costs. Much of Crohn's disease's indirect costs stem from afflicted individuals, in their prime earning years, having to leave the work force, accept lesser paying employment, use sick leave more often, and on job performance issues. The high cost of therapy just to daily function often forced individuals to seek disability status.

Globally, the massive fiscal expenditure to sustain individuals with Crohn's disease within society removes multi-billions of dollars, pounds, euros from their application to alternate pressing healthcare needs.

Conclusion

The cited administrative responses to Crohn's disease bring into question what force is so powerful that could influence federal agencies and governments per se to act contrary to their avowed purpose within the Public Trust?

Conflict of Interest

None.

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None.

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