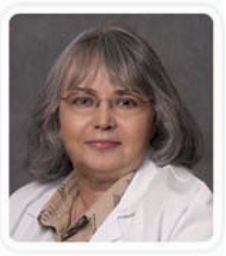
BREAST CANCER Prevention INSTITUTE REPORT April 2023

A Note from the President

By Angela Lanfranchi, MD FACS



I had originally planned to write the BCPI report about a common question patients have, "Can stress cause cancer?" There have been many articles and reviews about the subject. There may be a biological basis for this. We know depression, which often accompanies stress, adversely affects the immune system through the endocrine system. However, I've recently become concerned about our Federal Government's efforts to suppress the exchange of medical information through social media platforms that don't conform to Public Health Agencies of the Federal Government. Growing up in the late 60's and early 70's Science equaled Truth for me. It would never occur to me that a researcher might be dishonest in their findings. As a Clinical Assistant Professor at a medical school, I used to annually sign a statement that should I do research, I would not falsify the results. Dr. Fauci stated he was Science and he works for the Federal Government.

Recently, a web site that promotes natural family planning and has information about the adverse effects of hormonal contraception has been criticized and threatened by NewsGuard, an organization that received a $750,000 contract from the Department of Defense (DoD) to monitor "misinformation." Coincidently, the DoD also funded a 1997 study denying the ABC link 6 months after the first meta-analysis of ABC Link studies by Dr. Brind which showed an abortion link to breast cancer. I'm concerned as the threatened web site uses BCPI's information. In 2008 I wrote Federal and Academic Barriers to Informed Consent published in the *Journal of Physicians and Surgeons*. The paper can be downloaded from our web site under Resources/Publications. It details examples of the real misinformation that is published. I think we have to face the fact that there is scientific hegemony at work.

Our Hegemonic System of Public Health Science

By Angela Lanfranchi, MD FACS

Women's Health Jeopardized by Federal Agencies' Obfuscation

The National Cancer Institute (NCI) and Food and Drug Agency (FDA) are responsible for protecting the public's health. They both maintain websites which aver 1)The NCI mission is the " NCI leads, conducts, and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives." and 2) "The Food and Drug Administration is responsible for **protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs**, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA also provides accurate, science-based health information to the public."

Despite these lofty missions, both agencies have a long history of scientific hegemony injuring countless citizens. In 1924, the Ethyl Corporation, started by General Motors, the DuPont Corporation and Standard Oil, began to mass produce Ethyl. Ethyl was the proprietary named for gasoline containing patented tetraethyl lead (TEL), a gasoline additive which eliminated engine knock. Engine knock was preventing widespread use of the automobile but soon after Ethyl was introduced registered automobiles tripled. However, major health problems soon arose in a New Jersey facility manufacturing Ethyl. Eight workers died in delirium from lead poisoning and 300 other workers were made ill in the first 18 months of operation.

Initiated by the U.S. Surgeon General as the leader of the U.S. Public Health Service, a committee was appointed to investigate the health hazards of TEL. In May of 1925 the committee of six medical experts from Harvard, Yale, Johns Hopkins, Vanderbilt, the University of Chicago, and the University of Minnesota met with over 100 representatives of labor groups, oil companies, universities, government agencies, and news organizations. The committee began work in June 1925 and in the fall, reviewed a PHS-sponsored study of workers exposed to TEL

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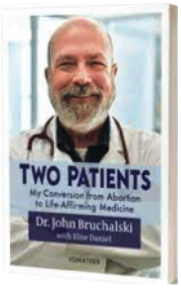
Co-founder & Board Member Publishes Book



Dr. John Brushalski M.D. who is a co-founder of BCPI and the founder of the Tepeyac Family Center recently became a published author recounting his personal and professional life story. It describes his training as an Ob-Gyn and how his practice of obstetrics changed when he faced an epiphany that his specialty treated two patients, mother and child. The book has had uniformly good reviews and is widely available at Amazon, bookstores, Walmart, Target, etc., etc., A great, great read.

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in garages and filling stations in Cincinnati and Dayton. The two studies found some "stippling" damage to red blood cells but no obvious external signs of clinical lead poisoning in muscle strength or gum color. However, Reed Hunt, the Harvard expert, had made a miscalculation in calculating how much lead workers were exposed to. In fact, when recalculated in the 1960s, the amount of lead exposure was much higher. So despite some reassuring findings of safety from lead exposure, the committee's report in January of 1926 concluded "**Longer exposure may show** that even such slight storage of lead as was observed in these studies **may lead eventually in susceptible individuals to recognizable lead poisoning** or chronic degenerative disease of obvious character... The committee feels this investigation must not be allowed to lapse." (Emphasis added) In other words, more studies were needed. There being no prohibition, factories using TEL went back to production within weeks. Despite the deaths and illnesses of workers as well as the fact that lead has been a recognized toxin since Roman times, the committee report was rife with the qualifications such as "may" or "needs more study". Forty years later in 1961, a PHS study of Los Angeles, Cincinnati, and Philadelphia found high levels of lead in the local air samples—from 1.4 to 25 mg/m3(cubic meter) and high blood lead levels in many test subjects. It wasn't until public pressure concerning smog which resulted in the 1970 Clean Air Act that finally ended the use of TEL. The lead ruined the catalytic converter needed to clean specified emissions so leaded gas had to be eliminated. It was 54 years after the problem was identified. Ironically, lead was not removed because of the harm to people but the harm to the catalytic converter.

A 2005 article published in the *International Journal of Occupational and Environmental Health* by William Kovarik PhD. stated: "Early warnings were ignored by industry, and as leaded gasoline became more profitable, scientists willing to support industry were financed as guardians of the scientific criteria for lead's health impacts. …...The apparatus and authority of science became suborned as an instrument of profit for the lead mining, oil refining, and automotive industries. By the 1960s, a hegemonic system of occupational and public health science had been created around the lead issue. It is significant that only scientists from outside the usual disciplinary constraints challenged industry at the time." To illustrate, a proponent of TEL was Dr. Robert Kehoe who for 40 years produced research supporting its use. He was simultaneously a professor of physiology at the University of Cincinnati and the medical director of the Ethyl Corporation. But it was industry outsiders such as geochemist Clair Patterson, who exposed flaws in the scientific methods of the lead industries, and psychiatrist Herbert Needleman, whose epidemiologic studies correlated higher lead levels with lower IQ levels in children who tried to bring the truth out about the dangers of TEL.

Almost 100 years after the first scientific committee formed to evaluate the impact of TEL, Public Health scientific committees are still meeting to assess risk. Unfortunately, they are keeping alive the tradition of hegemonic science in public health. The NCI website has a section named PDQ. The PDQ health professional cancer information summaries are "part of the comprehensive, evidence-based, up-to-date cancer content made available as a public service of the NCI. They are intended to improve the overall quality of cancer care by informing and educating health professionals about the current published evidence related to individual cancer-related topics and support informed decision making between clinicians and patients." In the case of breast cancer, the Healthcare Professional PDQ describes the following:

Hormonal Contraceptive risk as Factors and Interventions with Inadequate Evidence of an Association

"Oral contraceptives (OCPs) have been associated with a **small increased risk of breast cancer** in current users that diminishes over time. A well-conducted case-control study did not observe an association between breast cancer risk and oral contraceptive use for ever use, duration of use, or recent use. Another case-control study found no increased risk of breast cancer associated with the use of injectable or implantable progestin-only contraceptives in women aged 35 to 64 years. A nationwide **prospective cohort study in Denmark** found that women who currently or recently used hormonal contraceptives **had a higher risk of breast cancer** than did women who had never used hormonal contraceptives. Moreover, the risk of breast cancer increased with longer duration of hormonal contraceptive use. However, in absolute terms, the effect of oral contraceptives on breast cancer risk was very small; approximately one extra case of breast cancer may be expected for every 7,690 women using hormonal contraception for 1 year." That information might make it seem a negligible risk.

What this paragraph didn't say was the Denmark study was of 1.8 million women who were followed for 10.9 years. The average risk found was statistically significantly increased to 20%. To put that in perspective, on the same PDQ site a study of hormone replacement therapy (HRT) containing these same drugs in lower doses with less potency was found to have a statistically significant increased risk of 24% and was listed as evidence of an increased risk that could be avoided. If fact, in 2002 when the public became aware of that, 37 million women stopped their HRT and breast cancer rates went down for post-menopausal women and have remained lower since then. At the present time, there are 9 million women on oral contraceptives and another 3 million on other hormonal contraceptive formulations. Certainly some women would choose to use an equally effective contraceptive method that does not use hormones and the number of cases of premenopausal breast cancer would undoubtedly decrease.

On a different page at the NCI website regarding oral contraceptives there is the statement: "Overall, however, these studies have provided consistent evidence that the risks of breast and cervical cancers are increased in women who use oral contraceptives…" This is a straightforward statement that is absent in the PDQ section concerning prevention of breast cancer, i.e. informing health care professionals and patients of modifiable risks they can choose to avoid.

This is not at all the position of the FDA whose mission is to "…protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs…" . As reported previously in the April 2020 BCPI Report's "A note from the President"

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(available on the BCPI web-site) , a 98 page Citizens Petition was submitted and accepted by the FDA requesting modifications of the manufacturers package insert regarding the risks of hormonal contraceptives on May 9, 2019. The petition was lengthy due to the many risks that are omitted or reported with inaccurate data diminishing the impact of the risks involved. The entire FDA Citizens Petition by the Contraceptive Study Group (CSG) can be found under the Resources tab in News Updates or in Books in Health, Hormones and Contraception on the BCPI web-site. The petition is on the FDA web site at www.regulations.gov/docket/FDA-2019-P-2289.

Now, three years later in a 19 page letter dated May 17, 2022, the FDA has responded to the Contraceptive Study Group about the petition's section on the risk of breast cancer. Acknowledging that it was only a partial response to the entire petition, they stated that they had issued on April 29,2022 approvals for the following labeling changes to package inserts regarding breast cancer. They stated they based their recommendations on 6 studies they reviewed and assessed which they believed represented "…the most recent and best epidemiologic evidence on the risk of breast cancer..."of combined oral contraceptive users. The complete response letter is available on-line at the BCPI website under Resources tab/News Updates and on the FDA site at www.regulations.gov/document/FDA-2019-P-2289-0183

In the Patient Package Insert added information was given in question and answer form. Specifically: "Do birth control pills cause cancer?
It is not known if hormonal birth control pills cause breast cancer. **Some studies**, but not all, suggest there could be a **slight increase in the risk** of breast cancer among current users with longer duration of use. If you have breast cancer now, or have had it in the past, do not use hormonal birth control because some breast cancers are sensitive to hormones."

In the Manufacturers Insert, under the Warnings and Precautions heading, they stated that the drug was "contraindicated in females who currently have or have had breast cancer". In other words, don't take birth control pills if you already have breast cancer, now or in the past. Under the heading Adverse Reactions, they acknowledged 5 studies during "Postmarketing Experience" showed that breast cancer of ever users and never users showed no association but that two of three studies of current and recent users did show a statistically significant increase in breast cancer risk of up to 40% with 8-10 years of use. In other words, there was the equivocation that said; in essence "some studies say yes, some studies say no." It's unfortunate the FDA's response was before the latest study on breast cancer risk was published March 23, 2023 in Plos Medicine available on BCPI website under Resources/ News Updates. The research data was from a UK primary care data base. It was a strong prospective study of 9,498 women <50 years old diagnosed with breast cancer 1996-2017 with 18,171 closely matched controls. Overall, all forms of hormonal contraception elevated breast cancer risk with statistical significance. There was much public fanfare being reported on U.S. national television news programs.

So far, the FDA has only reviewed the CSG's Petition in regards to breast cancer as a risk due to hormonal contraceptive use. Breast cancer is an important risk to consider first because it is the most common cancer after skin cancer in women. In 2022 there were 42,465 deaths from breast cancer. The FDA still needs to review the Petition's data regarding the increased risk of HIV Transmission, Cervical Cancer, Crohn's Disease, Ulcerative Colitis, Systemic Lupus Erythematosus, Depression, Multiple Sclerosis, Interstitial Cystitis, Osteoporotic Bone Fracture, Increased Body Mass, Venous Thromboembolism, Atheroscelosis and Cardiovascular Events. The reader may suspect a question of whether or not the matter of hormonal contraception as a risk for breast cancer has been subjected to scientific hegemony. There is conflicting data on the NCI web site regarding the risk. There is minimization of the results of studies (e.g. 20% increase vs. one extra case of breast cancer may be expected for every 7,690 women), the information that some studies showed a risk while others did not and the use of qualifiers such as 'may 'or 'probably' which makes decision making difficult.

The NCI works closely with the International Agency for Research on Cancer (IARC) which is a part of the United Nation's World Health Organization. The task of the IARC is to "identify the causes of cancer so that preventive measures may be adopted and the burden of disease and associated suffering reduced." This is a lofty goal. In 2007, the IARC published Monograph 91 on Combined Estrogen-Progestogen Contraceptives and Combined Estrogen-Progestogen Menopausal Therapy. The comprehensive nearly 500 page document concluded that these combination drugs were Group 1 carcinogens for breast, cervical and liver cancer. Group 1 means "there is sufficient evidence of carcinogenicity in humans." There is no hedging. Yet there was no mention of this evaluation on the NCI website. When the leader of the IARC group was asked how the group arrived at that decision of Group 1 classification, he alluded to the fact that no one in that group was allowed to vote except those scientists who had not worked for or received grants from pharmaceutical companies that made those drugs. He was responding to the uproar that occurred on publication of Monograph 91.

It is very difficult to believe that scientists would not be truthful in the analysis of data. Yet the fact that a significant portion are not

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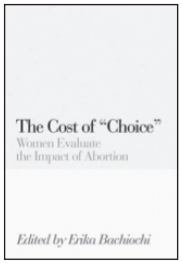
truthful has been established through study. In 2005, published in *Nature*, a study by Martinson, Anderson, and de Vries found that 20.6 % of mid-career scientists who had been given funds by the National Institutes of Health (NIH) including the NCI admitted in an anonymous survey to "Changing the design, methodology or results of a study in response to pressure from a funding source" i.e. NIH. There were 3,247 scientists who participated in the survey. This result was statistically significant. Clearly this affects scientific integrity and creates mistrust.

Many older people are aware that cigarettes were once advertised as healthful. Doctors smoking in advertisements were common. Some cigarettes were touted as low tar, as some hormonal contraception is deemed low estrogen. The evidence that smoking caused lung cancer was in the medical literature for 40 years before 1964 when the U.S. Surgeon General informed the public. In those 40 years, lung cancers went from being rare to reaching epidemic levels. It is still the most deadly cancer. The head of the NCI is a Presidential political appointee. During those 40 years, political pressure by tobacco state Senators kept the link between lung cancer and tobacco obscured. The American Medical Association (AMA) initially supported the Surgeon General's initiative to put warnings on cigarette packs. They withdrew their support when offered several million dollars to do more studies for the Tobacco Institute. In other words, "some studies say, some studies say no". At the present time, there is a political drive to create policy to combat climate change caused by fossil fuels used by people. People are perceived to negatively impact the Earth, Mother, Gaia. The fewer people the better. Contraception and abortion reduce the human population. This is perceived as good for the Earth. The Federal Government funds 82% of research grants. Circumstances are ripe for continued scientific hegemony.

The Cost of Choice

In 2004, Erika Bachiochi edited a book, *The Cost of Choice*. As reviewed in Goodreads.com, " Law professor Elizabeth Schiltz describes the unsettling reactions she faced for "choosing" to give birth to a child with Down Syndrome. Dr. Angela Lanfranchi, co-founder of the Breast Cancer Prevention Institute, offers evidence supporting a link between induced abortion and increased risk of breast cancer. Psychiatrist Joanne Angelo tells how abortion has affected women she has treated. With essays by emminent women such as Mary Ann Glendon, Learned Hand Professor of Law at Harvard Law School, and Elizabeth Fox-Genovese, Eleonore Raoul Professor of the Humanities at Emory University, The Cost of Choice shows another side of feminism and captures the complexity of a divisive social issue."

Now due to the FDA Petition we know the cost of choosing hormonal contraception: over 1 million cases of additional diseases and roughly $16.8 billion dollars. The petition includes data from over 180 published studies covering the various risks associated with hormonal contraceptives. It also includes statements on environmental impact and an economic analysis.



The table below summarizes the excess burden, in human and economic terms, of these largely unacknowledged health risks from hormonal contraceptives. (A negative number is fewer cases or less cost.)

Estimated Total Burden of Disease and Economic Costs

Disease	Estimated Excess Cases	Estimated Excess Costs
HIV	10,686	US$157,218,081
Breast cancer	452,930	US$10,021,975,916
Cervical cancer	76,581	US$1,052,914,912
Crohn's disease	81,762	US$1,910,583,605
Ulcerative colitis	40,526	US$522,789,187
Systemic lupus erythematosus	20,385	US$438,985,908
Depression combined oral contraceptives (COCs)	377,733	US$2,413,713,761
Depression progesterone-only contraceptives (POCs)	146,711	US$937,482,772
Interstitial cystitis	12,345	US$89,165,215
Fractures COCs	26,471	US$308,521,992
Fractures POCs	24,926	US$290,517,770
Myocardial Infarction	3,222	US$61,062,935
Cerebrovascular Accident	6,158	US$116,719,504
Hyperthyroidism	-1,748	-US$3,956,680
Uterine cancer	-198,808	-US$628,302,197
Ovarian cancer	-31,487	-US$820,419,141
Totals	1,048,393	US$16,868,973,540