

#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

DIVISION OF CORPORATION FINANCE

March 20, 2013

Sanford J. Lewis sanfordlewis@strategiccounsel.net

Re: Danaher Corporation Incoming letter dated March 13, 2013

Dear Mr. Lewis:

This is in response to your letter dated March 13, 2013 concerning the shareholder proposal submitted to Danaher by Trinity Health, the Dominican Sisters of Hope, the Benedictine Sisters of Baltimore, Providence Trust, and Catholic Health East. We also have received a letter from Danaher dated March 14, 2013. On March 8, 2013, we issued our response expressing our informal view that Danaher could exclude the proposal from its proxy materials for its upcoming annual meeting. You have asked us to reconsider our position. After reviewing the information contained in your letter, we find no basis to reconsider our position.

Under Part 202.1(d) of Section 17 of the Code of Federal Regulations, the Division may present a request for Commission review of a Division no-action response relating to Rule 14a-8 under the Exchange Act if it concludes that the request involves "matters of substantial importance and where the issues are novel or highly complex." We have applied this standard to your request and determined not to present your request to the Commission.

Copies of all of the correspondence on which this response is based will be made available on our website at <u>http://www.sec.gov/divisions/corpfin/cf-noaction/14a-8.shtml</u>. For your reference, a brief discussion of the Division's informal procedures regarding shareholder proposals is also available at the same website address.

Sincerely,

Jonathan A. Ingram Deputy Chief Counsel

cc: Ronald O. Mueller Gibson, Dunn & Crutcher LLP shareholderproposals@gibsondunn.com

## **GIBSON DUNN**

Gibson, Dunn & Crutcher LLP

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March 14, 2013

#### <u>VIA E-MAIL</u>

Office of Chief Counsel Division of Corporation Finance Securities and Exchange Commission 100 F Street, NE Washington, DC 20549

#### Re: Danaher Corporation

Shareholder Proposal of Trinity Health, the Dominican Sisters of Hope, the Benedictine Sisters of Baltimore, Providence Trust and Catholic Health East Securities Exchange Act of 1934—Rule 14a-8

Ladies and Gentlemen:

On January 14, 2013, we submitted a letter (the "Initial Request") on behalf of our client, Danaher Corporation (the "Company"), notifying the staff of the Division of Corporation Finance (the "Staff") of the Securities and Exchange Commission ("the Commission") that the Company intends to omit from its proxy statement and form of proxy for its 2013 Annual Meeting of Shareholders (collectively, the "2013 Proxy Materials") a shareholder proposal (the "Proposal") and statements in support thereof received from Trinity Health, the Dominican Sisters of Hope, the Benedictine Sisters of Baltimore, Providence Trust and Catholic Health East (collectively, the "Proponents").

The Initial Request indicated our belief that the Proposal could be excluded from the 2013 Proxy Materials pursuant to Rule 14a-8(i)(5) because the Proposal relates to operations that do not exceed the thresholds set forth in Rule 14a-8(i)(5) and is not otherwise significantly related to the Company's business, and pursuant to Rule 14a-8(i)(7) because the Proposal deals with a matter relating to the Company's ordinary business operations. On February 15, 2013 and February 25, 2013, the Proponents' representative, Mr. Sanford J. Lewis, submitted letters responding to the Initial Request, which we addressed in a letter dated February 28, 2013. Mr. Lewis submitted an additional letter on March 5, 2013. On March 8, 2013, the Staff issued a response to the Initial Request, concurring in our view that the Company may exclude the Proposal under Rule 14a-8(i)(7).

On March 13, 2013, Mr. Lewis submitted a letter (the "Reconsideration Request") requesting reconsideration and Commission review of the Staff's March 8, 2013 decision. The

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Reconsideration Request cites a number of statements and sources that we believe are taken out of context and, as with the Proposal and Proponents' prior submissions, addresses generalized issues regarding mercury that are not related to or particularized to dental amalgam. However, the Reconsideration Request does not raise any issues regarding dental amalgam and the Proposal that were not already encompassed by the materials presented to the Staff in the correspondence preceding the Staff's March 8, 2013 decision.

Accordingly, based upon the foregoing analysis and the analysis in the Initial Request, we respectfully request that the Staff affirm its March 8, 2013 decision. In addition, we respectfully inform the Staff that the Company currently plans to begin printing the 2013 Proxy Materials on or about March 25, 2013, and we would appreciate receiving a response before that date.

We would be happy to provide you with any additional information and answer any questions that you may have regarding this subject. Correspondence regarding this letter should be sent to shareholderproposals@gibsondunn.com. If we can be of any further assistance in this matter, please do not hesitate to call me at (202) 955-8671 or James O'Reilly, Danaher's Associate General Counsel and Secretary, at (202) 419-7611.

Sincerely, enald O. Uvellen, ENE

Ronald O. Mueller

James F. O'Reilly, Danaher Corporation Sanford J. Lewis Catherine M. Rowan, Trinity Health Valerie Heinonen, Dominican Sisters of Hope Kathleen White, Benedictine Sisters of Baltimore Dianne Heinrich, Providence Trust Kathleen Coll, Catholic Health East

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cc:

#### SANFORD J. LEWIS, ATTORNEY

March 13, 2013

Lona Nallengara Acting Director Division of Corporation Finance U.S. Securities and Exchange Commission 100 F Street, N.E. Washington, D.C. 20549

Re: Shareholder Proposal Requesting a report on the environmental impacts of dental amalgam – Danaher – <u>Request for Reconsideration or Referral to the Commission</u>

Via email to shareholderproposals@sec.gov and nallengaral@sec.gov

Dear Ms. Nallengara,

I am writing to you on behalf of Trinity Health, The Benedictine Sisters of Baltimore, The Dominican Sisters of Hope, Providence Trust and Catholic Health East (collectively, the "Proponents"), who submitted a shareholder proposal (the "Proposal") to Danaher Corporation ("the Company" or "Danaher"). The proposal requests that the board issue a report summarizing Danaher's policies and plans for eliminating releases of mercury from Danaher dental amalgam.

I am writing to request reconsideration of the Staff decision of March 8, 2013, granting no action relief to the Company. A copy of this letter is being e-mailed concurrently to Ronald O. Mueller of Gibson, Dunn & Crutcher LLP, who represented the Company in prior correspondence.

The Staff decision of March 8 noted that "There appears to be some basis for your view that Danaher may exclude the proposal under rule 14a-8(i)(7), as relating to Danaher's ordinary business operations. In this regard, we note that the proposal relates to Danaher's product development. Proposals concerning product development are generally excludable under rule 14a-8(i)(7)."

For the reasons described below, we request reconsideration of the Staff's grant of the noaction letter and if reconsideration is denied that, pursuant to 17 CFR 202.1(d), the matter be presented to the Commission for its consideration.

#### **Brief Review and Analysis of Prior Correspondence**

In our prior correspondence on this matter, we cited prior Staff decisions in which proposals addressed matters of ordinary business, including product development, but were nevertheless treated as non-excludable pursuant to Rule 14a-8(i)(7) because they raised a significant policy issue. Some examples included nuclear products phaseout, *General Electric* (January 17, 2012, reconsideration denied March 1, 2012); phaseout of antibiotics in animal feed, *Tyson* 

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*Foods* (recon. granted December 15, 2009), and phaseout of fur products due to animal cruelty concerns, *Coach Inc.* (August 7, 2009). Each proposal related to product development or selection, but the presence of a significant policy issue caused the Staff to find that each Proposal was not excludable.

In our prior letters we had provided evidence that the use of mercury in dental amalgam raises a significant policy issue because it causes very harmful pollution and public health impacts:

Quantity of Mercury Usage in Dental Amalgam: Between 313 and 411 tons of dental mercury is consumed annually, making it one of the largest consumer uses of mercury worldwide.<sup>1</sup>

**Role of Dental Amalgam in Causing Pollution:** Approximately 50 percent of mercury entering local waste treatment plants comes from dental amalgam waste. It converts into methylmercury, a highly toxic form that builds up in fish, shellfish and animals that eat fish, including humans.

<u>Health impact of Mercury:</u> Fish and shellfish are the main sources of methylmercury exposure to humans. Mercury is a highly potent neurotoxin that is especially harmful to pregnant women, developing fetuses, and infants and children. Mercury can cause permanent damage to brain, kidneys and fetuses, and is particularly harmful to children and unborn babies because their nervous systems are still developing.<sup>2</sup> Based upon blood sampling data, federal scientists have estimated that between 300,000 and 630,000 infants are born in the United States each year with mercury levels that are associated, at later ages, with the loss of IQ.<sup>3</sup>

<u>Amalgam inevitably pollutes</u>: We discussed the opinions of experts that once dental amalgam is produced and used, mercury pollution is an inevitable outcome.

**Public controversy and debate:** We discussed how the prolonged controversy regarding public health implications of dental amalgam, including pollution, have led to debate being dubbed the "amalgam wars" with many in the dental and public health sectors choosing sides. As with the issue of nuclear safety, experts can be found either side of the debate, but there is

3 Mahaffey et al., Blood Organic Mercury and Dietary Mercury Intake: National Health and Nutrition Examination Survey, 1999 and 2000, Environmental Health Perspectives, April 2004. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241922/pdf/ehp0112-000562.pdf.

<sup>1</sup> United Nations Environmental Programme & Arctic Monitoring and Assessment Programme Report, "Technical Background Report to the Global Atmospheric Mercury Assessment," Arctic Monitoring and Assessment Programme / UNEP Chemicals Branch, 2008 page 20. (accessible at

http://www.chem.unep.ch/mercury/Atmospheric\_Emissions/Technical\_background\_report.pdf).

<sup>2</sup> U.S. Environmental Protection Agency, "Mercury Health Effects," http://www.epa.gov/mercury/effects.htm Studies in various states have documented levels of mercury in different locations, and different ages of impact on IQ. In Massachusetts, total mercury in blood samples collected during the second trimester of pregnancy was associated with reduced cognitive development in testing conducted at age 3 years, after adjusting for the positive effects of fish/seafood consumption during pregnancy.3 In the New York study, total cord blood mercury was associated with decreased IQ scores in testing conducted at age 4 years, after adjusting for the positive effects of consumption during pregnancy. http://www.epa.gov/ace/publications/ACE3\_2013.pdf, page 129.

no doubt of the existence or fervent opinions held in the debate, and this issue is not a fad war "flash in the pan" but a long lasting controversy that shows no sign of abating.

**Nexus to Company:** Danaher subsidiary Kerr is one of the major US producers of dental amalgam. It has the capacity to lead the sector's move away from dental amalgam.

#### **Applicable Commission and Staff Guidance**

In 1976 the Commission in Release 12999 (November 22, 1976) reviewed and reversed prior Staff determinations which had excluded shareholder proposals on ordinary business grounds and concluded that:

The Commission is of the view that the provision adopted today can be effective in the future if it is interpreted somewhat more flexibly than in the past. Specifically, the term "ordinary business operations" has been deemed on occasion to include certain matters which have significant policy, economic or other implications inherent in them. For instance, a proposal that a utility company not construct a proposed nuclear power plant has in the past been considered excludable under former subparagraph (c)(5) [now (i)(7)]. In retrospect, however, it seems apparent that the economic and safety considerations attendant to nuclear power plants are of such magnitude that a determination whether to construct one is not an "ordinary" business matter. Accordingly, proposals of that nature, as well as others that have major implications, will in the future be considered beyond the realm of an issuer's ordinary business operations, and future interpretative letters of the Commission's staff will reflect that view.

The same issue was discussed in Release 34-40018 (May 21, 1998) where the Commission stated that proposals that relate to ordinary business matters but that focus on "sufficiently significant social policy issues . . . would not be considered to be excludable because the proposals would transcend the day-to-day business matters."

In Staff decisions and Staff Legal Bulletins, the Staff has repeatedly confirmed that environmental and public health concerns are a significant policy issue. For instance, in Staff Legal Bulletin14C the Staff wrote:

To the extent that a proposal and supporting statement focus on the company minimizing or eliminating operations that may adversely affect the environment or the public's health, we do not concur with the company's view that there is a basis for it to exclude the proposal under rule 14a-8(i)(7).<sup>4</sup>

<sup>&</sup>lt;sup>4</sup> This was confirmed in Staff Legal Bulletin 14E: Staff Legal Bulletin 14E: To the extent that a proposal and supporting statement have focused on a company minimizing or eliminating operations that may adversely affect the environment or the public's health, we have not permitted companies to exclude these proposals under Rule 14a-8(i)(7).

#### Additional Evidence Regarding Dental Amalgam Phaseout as a Significant Policy Issue

We believe our prior correspondence clearly evidenced that dental amalgam phaseout implicates "operations that may adversely affect the environment or public health" and that non-exclusion of the proposal is consistent with prior Staff guidance and rulings. It is apparent to us that despite the above evidence, the Staff must not have found that the issue of dental amalgam phaseout, constituted a significant policy issue with a nexus to the Company. That is the only way we can reconcile the prior Staff decisions and guidance with the current decision.

This has caused us to review our prior submissions and consider whether we provided the Staff with sufficient evidence to confirm that this is significant policy issue that transcends ordinary business.

Although we believed that the evidence already provided shows that this proposal relates to a very substantial pollution and public health issue documenting a significant policy issue with a nexus to the Company, today we provide additional evidence to document this point.

In addition, we are aware that the Staff may use several additional criteria to determine whether a matter constitutes a significant policy issue, including informal indications that key criteria include level of public debate on the issue, with indicia such as media coverage, regulatory activity, high level of public debate and legislative activity. This document provides additional documentation on those issues as well.

Accordingly, we are pleased to provide additional information today to further support a finding that this Proposal is not excludable pursuant to Rule 14a-8(i)(7), and request that the Staff, or if necessary, the Commission, reverse the prior grant of no action relief.

# 1. A large amount of mercury pollution will inevitably be caused by the use of dental amalgam. This pollution is inevitable, so long as dental amalgam is utilized.

#### a. Amount of amalgam consumed exceeds other consumer uses of mercury

Dental amalgam, a commonly used dental filling material, is a mixture of mercury and a metal alloy. The normal composition is 45-55% mercury; approximately 30% silver and other metals such as copper, tin and zinc.<sup>5</sup>

To appreciate the extent of the dental mercury pollution problem, it is valuable to compare the amount of mercury being used for dental amalgam with the amount being used for other

<sup>&</sup>lt;sup>5</sup> http://www.who.int/water\_sanitation\_health/medicalwaste/mercurypolpaper.pdf

common mercury products. As noted above, between 313 and 411 tons of dental mercury are consumed annually around the globe, making it one of the largest consumer uses of mercury in the world.<sup>6</sup> The demand for dental mercury is higher than the demand for almost all other mercury products – more than lamps (120-150 tons), measuring and control devices (320-380 tons), and electrical devices (180-220 tons).<sup>7</sup> As other mercury products are being phased out, amalgam is fast becoming the largest source of mercury pollution from products.

According to the United Nations Environment Programme, the use of mercury in tooth fillings represents some 10% of global mercury consumption, thus being among the largest consumer uses of mercury in the world (AMAP/UNEP 2008).<sup>8</sup> In fact, so much amalgam is used that "The general population is primarily exposed to mercury through the diet and dental amalgam."<sup>9</sup>

#### b. Dental mercury pollution from cremation is increasing

Cremation of corpses containing mercury amalgam is a significant source of mercury and will increase rapidly as a pollution source for two reasons. First, the rate and number of cremations in the US is expected to grow rapidly. The Cremation Association of North America's 2007 trends analysis projects that in 2025, about 56% of all corpses will be cremated, for a total of 1,706,000 corpses.<sup>10</sup>

<u>http://www.chem.unep.ch/mercury/Atmospheric Emissions/Technical\_background report.pdf</u>}.
<sup>9</sup> NIH U.S. National Library of Medicine, Mercury Compounds: Human Health Effects, <u>http://toxnet.nlm.nih.gov/cgi-</u>

bin/sis/search/a?dbs+hsdb:@term+@DOCNO+6943

<sup>&</sup>lt;sup>6</sup> UNEP & AMAP, *Technical Background Report to the Global Atmospheric Mercury Assessment* (2008), <u>http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/Publications/Technical\_background\_rep\_ort.pdf</u> p.20

<sup>&</sup>lt;sup>7</sup> UNEP & AMAP, Technical Background Report to the Global Atmospheric Mercury Assessment (2008), <u>http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/Publications/Technical background rep</u> <u>ort.pdf</u> p.20

<sup>&</sup>lt;sup>8</sup>United Nations Environmental Programme& Arctic Monitoring and Assessment Programme Report, "Technical Background Report to the Global Atmospheric Mercury Assessment," Arctic Monitoring and Assessment Programme / UNEP Chemicals Branch, 2008 page 20. (accessible at

<sup>&</sup>lt;sup>10</sup> John Reindl, Summary of References on Mercury Emissions from Crematoria (25 Sept. 2012), http://www.ejnet.org/crematoria/reindl.pdf

#### **Cremation Data & Predictions: Data Trends**



#### Percentage of Deaths Resulting in Cremation Since 1985

Second, in the past, many of the deceased had false teeth, which, of course, have no fillings. But as baby boomers die, they still have many teeth with fillings. As a result, more amalgams will be cremated than in the past.

As a result of these trends, it is estimated that mercury released to the environment from cremation will increase from just under 3,000 to 7,700 kilograms a year in the U.S. by 2020.<sup>11</sup> A mercury flow worksheet developed for Region V of the EPA estimates that in 2005, just under 3,000 kilograms of mercury were released to the environment from cremation to the US. Another researcher, Michael Bender, estimates that this will increase to 7,700 kilograms by 2020.<sup>11</sup>

# c. Continued use of dental amalgam means continued and increasing pollution.

The Company attempted to argue in its letters that the production and sale of dental amalgam does not imply the inevitable creation of pollution, but rather that the pollution comes from secondary sources such as improper disposal. However, available evidence confirms that as long as dental amalgam is utilized, it will continue to cause pollution.

For instance, one might suggest that despite the increase in cremations, it could be possible to remove teeth prior to cremations. However, as a recent article in *MinnPost* summarized, there is great difficulty associated with pulling teeth to reduce mercury pollution from cremation. For instance:

<sup>&</sup>lt;sup>11</sup> John Reindl, Summary of References on Mercury Emissions from Crematoria (25 Sept. 2012), http://www.ejnet.org/crematoria/reindl.pdf

<sup>&</sup>lt;sup>12</sup> John Reindl, Summary of References on Mercury Emissions from Crematoria (25 Sept. 2012), http://www.ejnet.org/crematoria/reindl.pdf

• First, amalgam is difficult and time-consuming to remove from the dead. As a recent newspaper article explained, "So why not yank the filled teeth of those being cremated? Already, pacemakers are removed from bodies before cremation because it turns out that pacemakers can create small explosions in the cremation process that damage crematorium tiles. But, unlike teeth, pacemakers are simple to remove, according to the Cremation Society of Minnesota's Kevin Waterston, who lobbies on behalf of the cremation business as well as other mortuary services. Pacemakers, he explained, are small and just beneath the surface of the skin. With just a couple of snips, the pacemaker can be removed. Teeth, however, are a much bigger problem. Rigor mortis, in the hours immediately following death, makes getting at teeth difficult. If a body is to be displayed at a funeral before cremation, removal of teeth can deform the face."<sup>13</sup>

Second, because removal is difficult and time-consuming, it adds to the costs of cremation. "So why not yank away?...The industry lobbyists fight it, saying it would be costly and time consuming."<sup>14</sup>

• Third, removing amalgam from dead bodies raises issues of dignity and religious issues as well.<sup>15</sup> Pulling teeth involved removal of a body part and removing amalgam from the teeth subjects the body to an involved dental procedure that damages teeth.

- Fourth, some state laws can hinder the removal of amalgam from dead bodies. According to the Cremation Society of Minnesota's Kevin Waterston, under state law, only licensed morticians can handle bodies. But some crematoriums do not have licensed morticians on staff.<sup>16</sup>
- Fifth, it is unclear how crematories are to dispose of amalgam. Would new regulations require them to dispose of the mercury properly or to recycle it? Or would it just end up in the environment by another means, such as through a landfill. Dentists who remove amalgam should use amalgam separators would crematories remove whole teeth or remove just the amalgam, in which case would they need to buy separators too? Unlike amalgam manufacturers, crematories have no way to phase down the amount of amalgam used; they take the bodies as they come. So far from the "polluter pays" principle, ensuring the proper disposal

<sup>&</sup>lt;sup>13</sup> Doug Grow, Regulating cremations' mercury emissions proves as hard as pulling teeth (18 February 2012), <u>http://www.minnpost.com/politics-policy/2013/02/regulating-cremations-mercury-emissions-proves-hard-pulling-teeth</u>

<sup>&</sup>lt;sup>14</sup> Doug Grow, Regulating cremations' mercury emissions proves as hard as pulling teeth (18 February 2012), <u>http://www.minnpost.com/politics-policy/2013/02/regulating-cremations-mercury-emissions-proves-hard-pulling-teeth</u>

<sup>&</sup>lt;sup>15</sup> Doug Grow, Regulating cremations' mercury emissions proves as hard as pulling teeth (18 February 2012), <u>http://www.minnpost.com/politics-policy/2013/02/regulating-cremations-mercury-emissions-proves-hard-pulling-teeth</u>

<sup>&</sup>lt;sup>16</sup> Doug Grow, Regulating cremations' mercury emissions proves as hard as pulling teeth (18 February 2012), <u>http://www.minnpost.com/politics-policy/2013/02/regulating-cremations-mercury-emissions-proves-hard-pulling-teeth</u>

of amalgam by crematoria will stick these often small businesses with the bill for the pollution caused by large amalgam manufacturers.

Similarly, it is sometimes argued that dental mercury pollution problems can be addressed by implementing best management practices in dental offices like installing amalgam separators to catch some amalgam before it enters the wastewater. But with most of the mercury walking out of dental offices in patients' teeth, managing amalgam waste with separators and best management practices alone "is not sufficient in itself to address the whole range of mercury releases from the dental amalgam life cycle...," according to European Commission consultant BIO Intelligence Service (BIOIS).<sup>17</sup>

Best management practices like separators, while necessary to address amalgam already in circulation, are insufficient to address the larger problem of dental mercury pollution for three reasons:

- First, many separators if they are installed at all are not properly maintained: "a significant proportion of separators are not adequately maintained, which reduces significantly their mercury capture efficiency," says BIOIS.<sup>18</sup>
- Second, governments pay the high cost of enforcing best management practices. Dentists do not voluntarily install and maintain separators (in the EU alone, at least 25% of dental clinics do not have separators at all despite EU waste legislation).<sup>19</sup> BIOIS explained that governments would have to pay for "increased awareness raising activities towards dental clinics and/or a higher frequency of inspections of dental clinics in order to ensure that EU waste legislation is fully complied with...assuming that each inspection (including a visit and some time for reporting) would take approximately 4 hours and that 10% of EU dental clinics would be inspected each year, this would result in approximately 35,000 hours annually in the EU27, corresponding to approximately 1 million EUR/year of labour cost for public authorities."<sup>20</sup>
- Third, BIOIS concludes that managing amalgam waste alone "is not sufficient in itself to address the whole range of mercury releases from the dental amalgam life cycle (it does not address mercury releases from the natural deterioration of amalgam fillings in people's mouths, from cremation and burial, and residual emissions to

<sup>19</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV,

http://ec.europa.eu/environment/chemicals/mercury/pdf/Final\_report\_11.07.12.pdf, p.11

<sup>20</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV,

http://ec.europa.eu/environment/chemicals/mercury/pdf/Final\_report\_11.07.12.pdf, p.89

<sup>&</sup>lt;sup>17</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV,

 <sup>&</sup>lt;u>http://ec.europa.eu/environment/chemicals/mercury/pdf/Final\_report\_11.07.12.pdf</u>, p.108
<sup>18</sup> BIO Intelligence Service (2012), *Study on the potential for reducing mercury pollution from dental amalgam and batteries*, Final report prepared for the European Commission-DG ENV,

http://ec.europa.eu/environment/chemicals/mercury/pdf/Final report 11.07.12.pdf, p.11

urban WWTPs).<sup>21</sup> Only ending amalgam use would "allow a significant reduction of dental mercury releases within the next 15 years and would virtually eliminate the environmental impacts of dental mercury in the longer term.<sup>22</sup>

Sometimes it is also claimed that amalgam is a lesser source of mercury pollution than coalfired power plants. Thermometers are also a much smaller source than amalgam, yet governments are still trying to phase-out mercury-based thermometers. This is because even small amounts of anthropogenic mercury, like those coming from thermometers, can have serious effects in the environment. As the Interstate Mercury Education and Reduction Clearinghouse (IMERC) has explained, "Approximately one gram of mercury, the amount in a single fever thermometer, is deposited to a 20-acre lake each year from the atmosphere. This small amount, over time, can contaminate the fish in that lake."<sup>23</sup> When just a small amount of anthropogenic mercury can do this much damage, the problem cannot be solved unless all sources are addressed.

#### 2. Level of Harm

In a press release, the U.S. Environmental Protection Agency stated that once dental amalgam is in the environment, "certain microorganisms can change elemental mercury into methylmercury, a highly toxic form that builds up in fish, shellfish and animals that eat fish. Fish and shellfish are the main sources of methylmercury exposure to humans. Methylmercury can damage children's developing brains and nervous systems even before they are born."<sup>24</sup>

# As a result, EPA estimates that more than 300,000 newborns each year may have increased risk of learning disabilities associated with in utero exposure to methylmercury.<sup>25</sup> Many studies have affirmed the link between mercury exposure and IQ:

• A 2005 analysis of three epidemiological studies found that prenatal mercury exposure sufficient to increase the concentration of mercury in maternal hair at childbirth by 1 ug/g decreases IQ by 0.7 points.<sup>26</sup>

<sup>23</sup> http://www.newmoa.org/prevention/mercury/mercurylake.pdf

<sup>&</sup>lt;sup>21</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV,

http://ec.europa.eu/environment/chemicals/mercury/pdf/Final\_report\_11.07.12.pdf, p.108

<sup>&</sup>lt;sup>22</sup> BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission-DG ENV,

http://ec.europa.eu/environment/chemicals/mercury/pdf/Final\_report\_11.07.12.pdf, p.19

<sup>&</sup>lt;sup>24</sup>EPA (2010),

http://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/a640db2ebad201cd852577ab0063 4848!OpenDocument

<sup>&</sup>lt;sup>25</sup> EPA, Human Exposure, http://www.epa.gov/hg/exposure.htm

<sup>&</sup>lt;sup>26</sup> Cohen, J.T., Bellinger, D.C., and Shaywitz, B.A. (2005), A Quantitative Analysis of Prenatal Methyl Mercury Exposure and Cognitive Development, American Journal of Preventive Medicine, Volume 29, Issue 4, November 2005. (cited in Health Care Without Harm & Health and Environmental Alliance, Halting the Child Brain Drain: Why We Need to Tackle Global Mercury Contamination (Dec. 2006), <u>http://www.env-health.org/IMG/pdf/2-</u> Halting the child brain drain Why we need to tackle global mercury contamination.pdf)

- In another 2005 study in the US, levels of maternal hair mercury at delivery were correlated with 6-month infant cognition. Offspring of mothers with hair mercury above 1.2  $\mu$ g/g had lower scores for cognition tests than those with hair mercury below 1.2  $\mu$ g/g.<sup>27</sup>.
- Exposure to neurotoxic chemicals like lead and methyl mercury could reduce the number of children with far above average intelligence (IQ scores above 130 points), and might likewise have increased the number with IO scores below 70.<sup>28</sup> For example, a 2005 study found that between 316,588 and 637,233 children in the US have cord blood mercury levels greater than 5.8ug/l, a level reported to be associated with loss of IQ.; other neurodevelopmental effects may also occur at that level with similar implications. One way to measure the cost of methyl mercury toxicity is by lost productivity; this study estimates these losses at \$8.7 billion annually (range \$2.2 -43.8 billion).<sup>29</sup> As the study explains, "This significant toll threatens the economic health and security of the United States and should be considered in the debate on mercury pollution controls."<sup>30</sup>

The IQ effects of mercury exposures may be significantly higher for populations that are especially reliant on fish in the diet, such as Native Americans and Asian Americans, making mercury pollution a serious environmental justice issue as well.<sup>31</sup>

The United Nations Environmental Programme says, "Mercury is recognized as a chemical of global concern due to its long-range transport in the atmosphere, its persistence in the environment, its ability to bioaccumulate in ecosystems and its significant negative effect on human health and the environment. Mercury can produce a range of adverse human health effects, including permanent damage to the nervous system, in particular the developing nervous system. Due to these effects, and also because mercury can be transferred from a mother to her unborn child, infants, children and women of child bearing age are considered vulnerable populations."<sup>32</sup>

Halting the child brain drain Why we need to tackle global mercury contamination.pdf) <sup>28</sup> Grandjean, P., Landrigan, PJ., (2006), Developmental neurotoxicity of industrial chemicals, The Lancet, November 8, 2006 DOI:10.1016/50140-673(06)69665-7 (cited in Health Care Without Harm & Health and Environmental Alliance, Halting the Child Brain Drain: Why We Need to Tackle Global Mercury Contamination (Dec. 2006), http://www.env-health.org/IMG/pdf/2-

113:590-596 (2005), http://www.ncbi.nlm.nih.gov/pubmed/15866768

<sup>31</sup> Concorde East West, The Real Cost of Dental Mercury (2012),

<sup>&</sup>lt;sup>27</sup> Oken e al. (2005), Maternal Fish Consumption, Hair Mercury, and Infant Cognition in a U.S. Cohort. VOLUME 113 | NUMBER 10 | October 2005 • Environmental Health Perspectives. (cited in Health Care Without Harm & Health and Environmental Alliance, Halting the Child Brain Drain: Why We Need to Tackle Global Mercury Contamination (Dec. 2006), http://www.env-health.org/IMG/pdf/2-

Halting the child brain drain Why we need to tackle global mercury contamination.pdf)

Trasande, Leonardo., Landrigan, Philip J., & Schechter, Clyde., (2005), Public Health and Economic Consequences of Methyl Mercury to the Developing Brain, Mount Sinai School of Medicine, New York, Environ Health Perspect 113:590-596 (2005) (cited in Health Care Without Harm & Health and Environmental Alliance, Halting the Child Brain Drain: Why We Need to Tackle Global Mercury Contamination (Dec. 2006), http://www.env-

health.org/IMG/pdf/2- Halting the child brain drain Why we need to tackle global mercury contamination.pdf) Trasande, Leonardo., Landrigan, Philip J., & Schechter, Clyde., (2005), Public Health and Economic Consequences of Methyl Mercury to the Developing Brain, Mount Sinai School of Medicine, New York, Environ Health Perspect

http://www.zeromercury.org/index.php?option=com phocadownload&view=file&id=158:the-real-cost-of-dentalmercury&Itemid=70

<sup>&</sup>lt;sup>32</sup> UNEP, Reducing Risk from Mercury, http://www.unep.org/hazardoussubstances/mercury/tabid/434/default.aspx

# The impact of mercury pollution on these vulnerable populations is so significant that President Obama has spoken out about it in a State of the Union address: "I will not back down from protecting our kids from mercury poisoning..."<sup>33</sup>

Mercury pollution can also have adverse effects on wildlife including "multiple behavioral changes such as mating behavior, feeding habits, caring for offspring, numbers of offspring, energy and activity levels, etc. – not to mention a range of physiological changes that are often not apparent until exposures are relatively high."<sup>34</sup>

## A study published on the National Institutes of Health website shows how pervasive mercury exposure of the US population is. The study published in 2005 found that:

Data from the National Health and Nutrition Examination Survey (NHANES) beginning in 1999 provide population-based exposure estimates for United States overall. Methylmercury exposures among women of childbearing age are of particular concern because of methylmercury's developmental neurotoxicity. **Exposures of concern among women are estimated to occur in between ~6% to 8% of the 16-to-49-year-old age group based on data from NHANES; and in ~15% of this age and sex group if physiological factors such as the degree of transplacental transport of methylmercury are taken into consideration.** Subgroups with high fish consumption (e.g., many island and coastal populations, some persons of Asian ethnicity, some individuals following "healthy" diets) can have methylmercury exposures substantially higher than those reported among the NHANES examinees.<sup>35</sup>

Because mercury pollution from dental amalgam is depressing the IQ of a portion of our population, it seems clear that this public health issue is also an issue with serious social and economic implications for the United States and the world.

#### **Confirming Nexus to the Company**

As we noted prior correspondence, as a manufacturer of dental amalgam, this problem of mercury pollution begins with Danaher and other manufacturers. Danaher subsidiary Kerr includes the following information in a dental amalgam Materials Safety Data Sheet<sup>36</sup>

- <u>Hazardous ingredients;</u> mercury (Hg), 45-50%:
- <u>Hazard classification</u>; Very toxic; Dangerous for environment.

<sup>34</sup> Concorde East West, The Real Cost of Dental Mercury (2012),

http://www.zeromercury.org/index.php?option=com\_phocadownload&view=file&id=158:the-real-cost-of-dentalmercury&Itemid=70

<sup>&</sup>lt;sup>33</sup> President Obama, transcript of *The State of the Union address* (2012), <u>http://cnsnews.com/blog/craig-bannister/state-union-obama-sees-it</u>

<sup>&</sup>lt;sup>35</sup> http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1473138/

<sup>&</sup>lt;sup>36</sup> KERR Material Safety Data Sheet used in EU in accordance with Community Regulation 2006/1907/EC (R.E.A.C.H.) Revision Date: 20<sup>th</sup> May 2009; <u>http://www.kerrdental.eu/media/7418/msds\_contour.pdf</u>

- <u>Treatment for inhalation (breathing</u>): Remove to fresh air. Consult a physician
- <u>Unusual fire and explosive hazards</u>: High temperature increases vaporization of the mercury
- <u>Accidental Release Measures, Environmental Precaution</u>: Do not allow product to contaminate ground, drains and river.
- <u>Reclaiming Methods</u>: Vacuum area using commercially available mercury vapor depressants or specialized vacuum cleaner avoiding dust formation. Sweep up as much spillage as possible using absorbent material and transfer it in available containers. Use special mercury vacuum cleaner.
- <u>Handling and Storage, Handling precautions</u>: When mercury vapors are developed, use a mask with a filter for mercury vapor. Avoid eating or smoking in areas where mercury is handled or stored.
- <u>Suggested container(s)</u>: Use container provided by manufacturer.
- <u>Environmental precaution</u>: Avoid product dispersion into the environment.
- <u>Local Exhaust Ventilation</u>: Recommended to keep airborne vapors under exposure limits
- <u>Respiratory Protection</u>: When working in areas where exposure limits are exceeded, wear dusk mask with approved cartridge for mercury vapors.
- <u>Odor</u>: Odorless (both powder and liquid).
- <u>Hazardous decomposition products</u>: Mercury vapors.
- <u>Conditions to avoid</u>: High temperatures.
- <u>Toxicological Information</u>: Toxic for reproduction: May cause harm to unborn child.
- Effects for prolonged exposure: Chronic poisoning results in nervous irritability, weakness, tremors, gingivitis, erethism and greying of lens of eye. Medical condition aggravated; kidney disorder.
- Bioaccumulative potential: Mercury
- <u>Risk phases of all ingredients</u>: May cause harm to unborn child. Very toxic inhalation. Toxic: danger of serious damage to health by prolonged exposure through inhalation. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

#### **Congressional activities**

Dental amalgam has been an issue of ongoing interest in Congress. The most recent congressional hearings on amalgam were held before the U.S. House of Representatives Committee on Oversight and Government Reform Subcommittee on Domestic Policy on May 26, 2010.<sup>37</sup> Entitled *Assessing EPA's Efforts to Measure and Reduce Mercury Pollution from Dentist Offices*, the hearings focused on dental mercury pollution to both the water and the air, and specifically the failure of the EPA and American Dental Association's memorandum of understanding to work toward convincing dentists to voluntarily install amalgam separators to

<sup>&</sup>lt;sup>37</sup>U.S. House of Representatives Committee on Oversight and Government Reform Subcommittee on Domestic Policy, Assessing EPA's Efforts to Measure and Reduce Mercury Pollution from Dentist Offices (26 May 2010), <u>http://oversight.house.gov/hearing/assessing-epas-efforts-to-measure-and-reduce-mercury-pollution-from-dentist-offices/; http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg65133/pdf/CHRG-111hhrg65133.pdf</u>

reduce the amount of mercury entering the wastewater. In his opening statement, Chairman Dennis Kucinich outlined the significance of the dental mercury pollution problem: "The largest source of mercury air emissions is smoke from coalburning power plants, about 50 tons per year. The next tier of major mercury air emissions is attributable to incineration of automobiles and mercury switches and pollution from industrial and commercial boilers. Each of these emissions is about 71/2 tons per year. Today's hearing addresses what scientific evidence suggests may be an unrecognized member of that second tier of major source of mercury pollution. Currently, dentists use more than 20 tons of mercury per year in dental fillings, replacing or repairing current fillings or putting new fillings in."<sup>38</sup>

Prior hearings on this issue had been held on July 8, 2008 when the Subcommittee convened to discuss *Assessing State and Local Regulations to Reduce Dental Mercury Emissions.*<sup>39</sup> As the Chair explained, this was a continuation of hearings that had been held on amalgam on November 14, 2007. Those hearings were entitled *Environmental Risks of and Regulatory Response to Mercury Dental Fillings.*<sup>40</sup> Again, the Chairman confirmed that "Mercury is a danger for the environment, and dentistry seems to be a significant contributor to that environmental threat."<sup>41</sup>

An even earlier series of hearings were held in 2003 and 2002. On October 8, 2003, the House of Representatives Subcommittee on Human Rights and Wellness of the Committee on Government Reform held a hearing on *The environmental impact of mercury-containing dental amalgams*.<sup>42</sup> On May 8, 2003, the House of Representatives Subcommittee on Human Rights and Wellness of the Committee on Government Reform held hearings on *Consumer choice and implementing full disclosure in dentistry*, which focused on amalgam.<sup>43</sup> On November 14, 2002, the House of Representatives Committee on Government Reform held hearings on *Mercury in dental amalgams : an examination of the science*.<sup>44</sup>

<sup>43</sup> House of Representatives Subcommittee on Human Rights and Wellness of the Committee on Government Reform, Consumer choice and implementing full disclosure in dentistry (8 May 2003), http://www.gpo.gov/fdsys/pkg/CHRG-108hhrg87704/html/CHRG-108hhrg87704.htm

<sup>&</sup>lt;sup>38</sup>U.S. House of Representatives Committee on Oversight and Government Reform Subcommittee on Domestic Policy, Assessing EPA's Efforts to Measure and Reduce Mercury Pollution from Dentist Offices (26 May 2010), <u>http://oversight.house.gov/hearing/assessing-epas-efforts-to-measure-and-reduce-mercury-pollution-from-dentist-offices/; http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg65133/pdf/CHRG-111hhrg65133.pdf</u>

<sup>&</sup>lt;sup>39</sup> U.S. House of Representatives Committee on Oversight and Government Reform Subcommittee on Domestic Policy, Assessing State and Local Regulations to Reduce Dental Mercury Emissions (8 July 2008), http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg49972/pdf/CHRG-110hhrg49972.pdf

<sup>&</sup>lt;sup>40</sup> U.S. House of Representatives Committee on Oversight and Government Reform Subcommittee on Domestic Policy, *Environmental Risks of and Regulatory Response to Mercury Dental Fillings* (14 November 2007), http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg49626/pdf/CHRG-110hhrg49626.pdf

<sup>&</sup>lt;sup>41</sup> U.S. House of Representatives Committee on Oversight and Government Reform Subcommittee on Domestic Policy, Environmental Risks of and Regulatory Response to Mercury Dental Fillings (14 November 2007), http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg49626/pdf/CHRG-110hhrg49626.pdf

<sup>&</sup>lt;sup>42</sup> U.S. House of Representatives Subcommittee on Human Rights and Wellness of the Committee on Government Reform, *The environmental impact of mercury-containing dental amalgams* (October 8, 2003), http://www.gpo.gov/fdsys/pkg/CHRG-108hhrg91841/html/CHRG-108hhrg91841.htm.

<sup>&</sup>lt;sup>44</sup> House of Representatives the Committee on Government Reform held hearings on Mercury in dental amalgams : an examination of the science (14 Nov 2002), <u>http://www.gpo.gov/fdsys/pkg/CHRG-107hhrg84699/html/CHRG-107hhrg84699.html</u>

In addition to hearings, members of Congress have determined that the issue of dental mercury pollution is so significant that they have gone directly to the press. Rep. Diane Watson wrote an article in the *Huffington Post* that was particularly critical of dental amalgam manufactures: "Manufacturers of amalgam should have the burden of proving its safety. To date, they have never sought nor been given pre-market approval for their product. The FDA must hold amalgam manufacturers accountable."<sup>45</sup>

#### Comparison with the Tyson case

The current case compares favorably with the reconsideration granted in *Tyson Foods Inc.* (December 15, 2009).

In *Tyson*, the use of antibiotics in hog production and throughout the supply chain. Was not at first considered by the Staff to present a significant social policy issue, but upon reconsideration of a more complete presentation of the damage caused by antibiotics to public health and the environment worldwide, the Staff agreed that this was a significant social policy issue and should not be excluded. The harm caused by mercury and the magnitude of harm caused by mercury pollution from dental amalgam worldwide due to Kerr's sales globally are of similar severity and public profile. As in the Tyson case, the additional documentation of the public health implications provided today should persuade the Staff or Commission to find that this proposal is not excludable.

In particular, the evidence provided in Tyson was sufficient to show that practices in animal husbandry were endangering the health of millions of Americans. Similarly, the evidence provided above, shows that dental mercury amalgam also endangers the health of millions of Americans, especially some of our most vulnerable populations such as infants and pregnant women. The EPA estimate of 300,000 newborns per year with increased risk of learning disabilities due to mercury exposure ought to suffice to show that these issues are of comparable level of public harm and concern.

Also the present matter has higher visibility on the internet than the issue of antibiotics did in *Tyson*. In particular, we note that a Google search for "dental amalgam pollution" produces 110,000 results (search on March 12, 2013) These numbers exceed the numbers found in searches on Tyson – where a Google search for "animal feed' + antibiotics + health" produced only 18,700 hits.

#### Conclusion

In conclusion, we urge the Staff to reconsider its March 8 grant to Danaher of no action relief, and to deny the Company's request for a no action letter. In the event that upon reconsideration of the Staff decision, the Staff adheres to the earlier decision, please request the Commission to review the Staff determination.

<sup>&</sup>lt;sup>45</sup> http://www.huffingtonpost.com/rep-diane-watson/the-beginning-of-the-end- b 32394.html

Please phone me at 413 549-7333 with regard to any questions or needs for additional information.

Sincerels

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