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

P.E. 1/14/13



DIVISION OF CORPORATION FINANCE

March 8, 2013

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Received SEC

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

Re: Danaher Corporation Incoming letter dated January 14, 2013

ston, DC 20549

Dear Mr. Mueller:

This is in response to your letters dated January 14, 2013 and February 28, 2013 concerning the shareholder proposal submitted to Danaher by Trinity Health; the Benedictine Sisters of Baltimore; the Dominican Sisters of Hope; Providence Trust; and Catholic Health East. We also have received letters on behalf of the proponents dated February 15, 2013, February 25, 2013, and March 5, 2013. Copies of all of the correspondence on which this response is based will be made available on our website at http://www.sec.gov/divisions/corpfin/cf-noaction/14a-8.shtml. For your reference, a brief discussion of the Division's informal procedures regarding shareholder proposals is also available at the same website address.

Sincerely,

Ted Yu Senior Special Counsel

Enclosure

cc: Sanford J. Lewis sanfordlewis@strategiccounsel.net

March 8, 2013

Response of the Office of Chief Counsel Division of Corporation Finance

Re: Danaher Corporation Incoming letter dated January 14, 2013

The proposal requests that the board issue a report summarizing Danaher's policies and plans for eliminating releases of mercury from Danaher products.

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). Accordingly, we will not recommend enforcement action to the Commission if Danaher omits the proposal from its proxy materials in reliance on rule 14a-8(i)(7). In reaching this position, we have not found it necessary to address the alternative basis for omission upon which Danaher relies.

Sincerely,

Charles Lee Attorney-Adviser

DIVISION OF CORPORATION FINANCE INFORMAL PROCEDURES REGARDING SHAREHOLDER PROPOSALS

The Division of Corporation Finance believes that its responsibility with respect to matters arising under Rule 14a-8 [17 CFR 240.14a-8], as with other matters under the proxy rules, is to aid those who must comply with the rule by offering informal advice and suggestions and to determine, initially, whether or not it may be appropriate in a particular matter to recommend enforcement action to the Commission. In connection with a shareholder proposal under Rule 14a-8, the Division's staff considers the information furnished to it by the Company in support of its intention to exclude the proposals from the Company's proxy materials, as well as any information furnished by the proponent or the proponent's representative.

Although Rule 14a-8(k) does not require any communications from shareholders to the Commission's staff, the staff will always consider information concerning alleged violations of the statutes administered by the Commission, including argument as to whether or not activities proposed to be taken would be violative of the statute or rule involved. The receipt by the staff of such information, however, should not be construed as changing the staff's informal procedures and proxy review into a formal or adversary procedure.

It is important to note that the staff's and Commission's no-action responses to Rule 14a-8(j) submissions reflect only informal views. The determinations reached in these noaction letters do not and cannot adjudicate the merits of a company's position with respect to the proposal. Only a court such as a U.S. District Court can decide whether a company is obligated to include shareholder proposals in its proxy materials. Accordingly a discretionary determination not to recommend or take Commission enforcement action, does not preclude a proponent, or any shareholder of a company, from pursuing any rights he or she may have against the company in court, should the management omit the proposal from the company's proxy material.

SANFORD J. LEWIS, ATTORNEY

March 5, 2013

Office of Chief Counsel 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, Inc. – supplemental reply

Via email to shareholderproposals@sec.gov

Ladies and Gentlemen:

I have been asked by the Proponents to respond to the supplemental letter dated February 28, 2013, sent to the Securities and Exchange Commission Staff by Ronald O. Mueller of Gibson Dunn & Crutcher on behalf of Danaher Inc. A copy of this letter is being e-mailed concurrently to Ronald O. Mueller.

Reputation regarding dental amalgam is relevant to Danaher's core customer base.

In its latest letter, the Company asserts that because the dental amalgam business represents only a single product line within its dental business segment, the production of dental amalgam is immaterial to the Company's operations. However, at a minimum this issue is relevant to the Company because it is "otherwise significantly related," to its dental segment, and therefore exceeds the relevancy thresholds.

Although the dental amalgam, as a product, is only one product out of many for the dental segment of the company, the reputational impact of the Company's stance and activities on dental amalgam extends to its primary customer base, the dental community. Thus, there should be little question that its public stance will affect its reputation with its core customers. The Company implies in its reply that dental offices don't care about the Company's postures on dental amalgam, and its resistance to a needed phase out. But, over the last decade, dentists, have been trending away from using dental amalgam. Surveys now suggest that a majority of dentists — that is, a majority of the Company's core customers — do not use dental amalgam. This change appears to be a result of a combination of factors, both the superior cosmetic qualities of dental amalgam of alternatives, and also continuing public health concern about mercury.

The use of dental amalgam by dentists has been on the decline for the past 12 years, with the mean percent of decline for the past 12 years being 3.7% per year.¹ The usage of dental amalgam has decreased from 30.77 tons in 2001 to 13.52 tons in 2010.²

This decline in the use of dental amalgam has been accompanied by an even larger proportion of decline in the number of dentists who use dental amalgam in their practices. The independent dental educational institution, Clinical Research Associates, based in Orem, Utah, has surveyed dentists that read its newsletters beginning in 1985 regarding their use of dental amalgam. In 1985 only 3% of dentists surveyed stated that they do not use dental amalgam. By 2001, that number had risen to 27%, and by 2005, 32% of dentists who said their offices were amalgam free. A study published in *General Dentistry* confirmed that 31.6% of dentists surveyed were not using amalgam by 2005.³ A more recent survey by another organization, published in 2012, showed that only 48% of dentists were still using dental amalgam.⁴

As the number of dentists using dental amalgam has shrunk to less than a majority, the increasing sensitivities of this issue for this customer base is apparent.

It is entirely unreasonable for the Company to assume reputational immunity from this issue now that a majority of its customer base no longer uses dental amalgam, dental amalgam has been phased out in several countries and the U.S. Department of State has called for "the phase down, with the goal the eventual phase out" of amalgam.⁵ Unresponsive and resistant handling of this issue, as the Proponent believes the Company is engaged in, increasingly threatens its reputation by straying from its commitments to "constant progress" and "constant motivation to be even better and more innovative." Instead, it seems clear that such an apparent reactive stance positions the company as a rear-guard, circle the wagons type of company that is resisting change, not one that is proactive and innovative.

This surely would hurt the Company's reputation with those of its customers, as many as a majority of whom have themselves moved away from dental amalgam, and many of whom already view this as an archaic way of approaching dentistry.

¹ <u>Public Health Rep.</u> 2007 Sep-Oct; 122(5):657-63. Economic impact of regulating the use of amalgam restorations. Beazoglou T, Eklund S, Heffley D, Meiers J, Brown LJ, Bailit H.

Department of Craniofacial Sciences, School of Dental Medicine, University of Connecticut Health Center, 263 Farmington Ave., Farmington, CT 06030, USA. <u>beazoglou@nsol.uchc.edu; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1936958/</u>

² International Mercury Reduction Clearinghouse (IMERC), Northeast Waste Management Officials Association (NEWMOA) Mercury Added Products Database, Dental Amalgam, June 2012, http://imerc.newmoa.org

³ R. Haj-Ali, Survey of general dentists regarding posterior restorations, selection criteria, and associated clinical problems, Gen Dent. 2005 Sep-Oct;53(5):369-75, <u>http://www.ncbi.nlm.nih.gov/pubmed/16252541</u>

⁴ Journal of Biomedicine and Biotechnology, Volume 2012 (2012), Article ID 589569, 8 pages, doi:10.1155/2012/589569.

⁵ http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/INC3/United%20States.pdf

A vote from Danaher's 2009 proxy demonstrates that this issue is of clear interest to investors.

A prior shareholder proposal (attached to this letter in Exhibit C) was voted upon at Danaher regarding the health and environmental issues of dental mercury. At its 2009 annual meeting. 16.5% of the investors voted in favor of the proposal. This clear and significant support demonstrates that from the standpoint of shareholders, this issue is of interest.

That level of support would have been enough to make refiling possible under Rule 14a-8(i)(12) on re-submission guidelines⁶ even if the issue had been voted on for many years in a row. So, judging by the SEC's criteria, this issue already has proven and substantial investor interest as a significant policy issue on which they favor company action. It would be unfortunate for the Staff to deny shareholders the opportunity to weigh in on this issue once again, given the strong initial support for the Proposal.

Dental amalgam is a high visibility public issue and debate.

Moreover, despite the Company's arguments to the contrary, it is difficult to see how the issue of mercury pollution from dental amalgam could not be a significant policy issue. Over the past three years, under the aegis of the United Nations Environmental Program, the world has negotiated an entire treaty on the sole subject of mercury.

Dental mercury is one of a small number of products so significant it is addressed by name; for amalgam, there is a directive to phase down its use. The fact that the World Health Organization (WHO) would issue an entire paper on amalgam is itself evidence that amalgam is not only a high-profile issue but a controversial material.⁷

At least since 2008, the United States Food and Drug Administration has given constant attention to increasing the regulation of amalgam -- as has the Environmental Protection Agency since 2010.

Of course, the Proponent recognizes that those criteria are not directly applicable to the matter at hand, but they do show something about what the Staff considers to be substantial investor interest.

⁷ World Health Organization, FUTURE USE OF MATERIALS FOR DENTAL RESTORATION(2011). (accessible at http://www.who.int/oral_health/publications/dental_material_2011.pdf)

The Company attempts to downplay the activities of the WHO asserting that their report ascribes mercury pollution to improper waste management practices, the mishandling of the product by some end-users. Although those activities are mentioned in the report, that is not the only source of mercury pollution flagged by the report. The larger issue of mercury pollution from the use of dental amalgam in general is certainly core to the concerns of WHO. It is clear that the Company's narrow interpretation of the WHO report differs sharply from the proponent's interpretation. We devoted several pages of the previous response solely to the WHO report, including a table from the report, numerous direct quotations, backed by no fewer than 18 footnotes referencing pages or sections. It is manifest that WHO is aware of the quantity of dental mercury in the environment, deeply concerned about the public health impact of dental mercury in the environment, and insistent that a worldwide phasedown must begin. Having lost that argument, the Company now says WHO is concerned only about the misuse of dental mercury, which is indeed condemned in the report, but it is the use of amalgam which WHO says must be phased down. Manifestly, WHO supports a worldwide phasedown in the use of amalgam, and does so under its mandate to improve the world's health.

Page 4

The emergence of quality alternatives in recent years increases the rationale for calling for a transition away from amalgam. Danaher and Kerr are at risk of being challenged by governments, attacked in the press, and condemned by the public for continuing to promote amalgam sales on such a widespread basis when viable alternatives are available from the Company that are far less polluting to the environment.

Also, the issue of the continuation of use of dental amalgam has been a highly controversial public issue for the FDA. In 2009 the FDA adopted a rule allowing the continued use of dental amalgam.

"No final rule in FDA's modern history, or perhaps ever, has attracted this kind of organized opposition." ---FDA Webview -- See Exhibit B.

The level of controversy has been sufficient that only months after allowing continued use of dental amalgam, the FDA initiated a reconsideration process in 2011, and also began making acknowledgments regarding risks of amalgam to vulnerable populations. In December 2010, the FDA Advisory Committee urged the FDA to consider more recent studies regarding the impact of mercury amalgam fillings on children.

The dental amalgam controversy has also been the subject of congressional hearings. The most recent was on May 26, 2010 before U.S. House of Representatives Committee on Oversight and Government Reform Subcommittee on Domestic Policy.⁸ Testimony from the FDA at a prior hearing on amalgam held in 2007 clearly indicates the level of controversy: "Given the high level of interest in this proposed rule, FDA twice reopened the comment period and received more than 750 comments submitted to the docket. FDA received significant adverse public comments on the 2002 proposed rule. The majority of the comments stated that the Agency was not proposing enough restrictions on the marketing and use of dental amalgam and that the proposed special controls did not adequately address the potential health risks of the device."9 In 2009, Rep. Diane Watson and 31 co-sponsors sponsored H. Res. 648 -- expressing the need for enhanced public awareness of potential health effects posed by mercury." It focused almost entirely on amalgam.¹⁰ The American Dental Association opposed it,¹¹ again indicating that this is a controversial issue. Members of Congress have also expressed particular interest in holding dental amalgam manufacturers accountable, such as Rep. Diane Watson's 2006 article in the Huffington Post that explained "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."12

^{* &}quot;Assessing EPA's Efforts to Measure and Reduce Mercury Pollution from Dentist Offices", http://oversight.house.gov/hearing/assessing-epas-efforts-to-measure-and-reduce-mercury-pollution-from-dentistoffices/

⁹ http://www.hhs.gov/asl/testify/2007/11/t20071114a.html

¹⁰ http://beta.congress.gov/bill/111th-congress/house-resolution/648/text

¹¹ http://www.ada.org/news/739.aspx

¹² Rep. Diane Watson, The Beginning of the End of Mercury in Dentistry, HUFFINGTON POST (24 Oct. 2006), http://www.huffingtonpost.com/rep-diane-watson/the-beginning-of-the-end- b 32394.html

This issue has been covered by national media. For examples, see Exhibit A of this letter.

This is clearly a controversial policy issue within the dental community – often referred to as the "dental amalgam wars". The trade press publication *Dr. Bicuspid* gives Dental Awards each year and one of the categories is for "most controversial topic." Mercury in amalgam was a semi-finalist for the 2013 "most controversial" award.¹³ See examples, in Exhibit B, attached to this letter, for additional discussion of the issue by the trade press.

Already, the focus on this issue by policymaking bodies and nongovernmental organizations is beginning to turn the spotlight on the Company as one of the few makers of this product. Just because the Company produces an item that it believes to meet a public health need does not immunize the company from potential reputational damage from the company's resistance to phasing down, with the goal to eventual phase out the production of dental amalgarn, while increasingly encouraging broader use of environmentally safer alternatives.

Supply chain cases are relevant

What is important about *AT&T Inc.* (February 7, 2013) is that even though the company had a different relationship to the waste stream and pollution than the current company does, it was well situated to affect the outcome of the materials. The same is true in the current instance. Avoiding producing dental amalgam is probably the single best thing to do to keep dental amalgam's mercury out of the environment. The Company's leadership position on this issue, combined with innovation and customer education, can go a long way toward solving this social and environmental issue.

We stand by our prior letter in all aspects, and believe the proposal is not excludable under the asserted rules. We urge the staff to inform the Company that the SEC proxy rules require denial of the Company's no-action request. Please contact me at (413) 549-7333 with respect to any questions in connection with this matter.

Sanford Lewis Attorney at Law

cc: Marlee S. Myers, Morgan Lewis & Bockius LLP Kathleen Coll, Catholic Health East Valerie Heinonen, Dominican Sisters of Hope Catherine M. Rowan, Trinity Health

¹³ http://www.drbicuspid.com/index.aspx?sec=nws&sub=rad&pag=dis&ItemID=312122

Page 6

EXHIBIT C

PRIOR PROPOSAL REGARDING DENTAL MERCURY AT DANAHER 2009

Page 17

Chemical Safety - Mercury 2009 – Danaher Corp.

WHEREAS: Dental amalgam is a pre-Civil War device composed of approximately 50% mercury, a virulent reproductive toxicant and neurological toxicant. (A fact sheet prepared by the Dental Board of California in 2004 states that amalgam is 43% to 54% mercury.) In sharp contrast to dentistry, medicine generally transitioned out of using mercury by the end of the nineteenth century. Today, the Food and Drug Administration (FDA) even bans mercury in applications for animals.

Because of the mercury, amalgam arrives at a dentist's office with a skull-and-crossbones affixed. Mercury amalgam is so hazardous that a dentist must put a removed filling into a hazardous waste container.

The most common dental filling material today is resin composite. Since resin is interchangeable with amalgam, substantial numbers of general dentists – one study says 38%, another 52% – never place mercury amalgam. Scandinavian nations discontinued mercury amalgam as national policy.

Abandoning mercury amalgam would be profitable for Danaher. A 2007 Bank of America Securities report says ending amalgam sales would improve profits for Dentsply (Danaher's main dental products competitor), because resin is more profitable.

After years of inaction, the FDA radically changed its website in June 2008 – withdrawing claims that amalgam is safe and issuing this chilling advisory:

"Dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses." (www.fda.gov/cdrh/consumer/amalgams.html)

A 2008 JPMorgan report, referencing the June 2008 FDA advisory, states that amalgam manufacturers are now at risk for class-action lawsuits.

Detailed reports by major environmental groups claim dental mercury is the largest source of mercury in the nation's wastewater.

As the most vaporous heavy metal, mercury vapors, in the opinion of many experts, are a clear danger to dental workers and their unborn children. Danaher is at risk in states permitting employees to sue those who put toxicants in the workplace.

S. 906, the Mercury Export Ban Act of 2008, bans mercury exports; this law's lead sponsor was Senator, now President, Obama. We believe such action by our new President forecasts an Administration which may be tough on companies producing mercury-laden products.

An NAACP witness testified before Congress that lower-income patients get mercury fillings while wealthy ones don't. Continued production of amalgam puts Danaher's reputation at risk for abetting two-tiered dentistry.

We believe: (1) the lesser profits from amalgam compared to other dental filling materials, (2) growing risk of litigation from patients and from workers, (3) likely reputational injury to Danaher, a company priding itself for interest in the environment, plus (4) risk to long-term sales due to damage to Danaher's reputation for providing quality dental products to the poor as well as the rich – all point to the need to cease production of amalgam.

RESOLVED: Shareholders request that the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, not later than December 31, 2009, identifying policy options for eliminating exposure of the environment and dental consumers to mercury from Danaher products.

Report of vote on shareholder proposal from Danaher 10-Q for the Quarter ended July 3, 2009

http://www.sec.gov/Archives/edgar/data/313616/000119312509153251/d10q.h tm#toc82657_14

Table of Contents

6. To act upon a shareholder proposal requesting that Danaher's Board of Directors issue a report identifying policy options for eliminating exposure of the environment and dental consumers to mercury from dental amalgams sold by Danaher. The proposal was rejected by a vote of shareholders as follows:

Por	
Against	180,658,793
Abstain	40,730,297
Broker non-votes	18,714,455

Gibson, Durin & Crutcher LLP

1050 Connecticut Avenue, N.W. Washington, DC 20036-5306 Tel 202.955.8500 www.gibsondunn.com

Ronald O. Mueller Direct +1 202.955.8671 Fax: +1 202.530.9569 RMueller@glbsondunn.com

February 28, 2013

VIA E-MAIL

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

Re: Danaher Corporation Supplemental Letter Regarding the 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 "No-Action 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 Benedictine Sisters of Baltimore, the Dominican Sisters of Hope, Providence Trust and Catholic Health East (collectively, the "Proponents").

The No-Action 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 are 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 No-Action Request (the "First Response Letter" and the "Second Response Letter," respectively, and collectively, the "Response Letters"). We continue to believe the Proposal is excludable under Rules 14a-8(i)(5) and 14a-8(i)(7) for the reasons stated in the No-Action Request. We also wish to respond to the Response Letters.

Brussels - Century City - Dálfas - Denver - Duhai - Hong Kong - London - Los Angeles - Munich - New York Orange County - Palo Alto - Paris - San Francisco - São Paulo - Sugapore - Washington, D.C.

Office of Chief Counsel Division of Corporation Finance February 28, 2013 Page 2

The Response Letters claim that the Proposal surpasses the thresholds in Rule 14a-8(i)(5) because it relates to the Company's entire dental segment, which accounted for 13% of the Company's total annual sales in 2011. However, on the same page (page 3), the Response Letters also acknowledge that the Company's dental segment provides "a broad range of equipment, consumables and services." Clearly, the Proposal does not relate to the entirety of the Company's dental business; it focuses exclusively on the Company's dental amalgam product line, which as noted in the No-Action Request accounted for less than one-half of one percent of the Company's gross sales and net earnings for fiscal year 2012.

The Response Letters also spend almost a full page quoting and discussing the Company's statements about its commitment to quality, culminating in the unremarkable conclusion that "Kerr and its parent company Danaher are both clearly invested in their corporate reputations." Based on that observation, the next sentence concludes, "Therefore, under the terms of Rule 14a-8(i)(5) this Proposal is 'otherwise significantly related' to the Company's business." Under the standard advocated in the Response Letters, no proposal could be excluded under Rule 14a-8(i)(5) because (1) every company desires a good reputation and (2) virtually every proponent likely believes that its proposal is important to a company's reputation. Thus, the Proponents do not satisfy their burden of demonstrating that the Proposal is "otherwise significantly related" to the Company's business.²

¹ Similarly, the Company's 2012 Form 10-K states:

Today, our dental businesses develop, manufacture and market the following dental consumables and dental equipment:

- · orthodontic bracket systems and lab products;
- impression, bonding and restorative materials;
- · endodontic systems and related consumables;
- infection prevention products;
- implant systems;
- · diamond and carbide rotary instruments;
- · digital imaging and other visualization and magnification systems;
- air and electric handpieces and associated consumables; and
- treatment units.

Dental amalgams are one of the Company's "restorative materials."

² See Exchange Act Release No. 39093 (Sept. 18, 1997) ("The proponent carries the burden of demonstrating that the proposal is 'otherwise significantly related.' See Exchange Act Release No. 19135 (Oct. 14, 1982)."); Exchange Act Release No. 19135 (Oct. 14, 1982) ("Where the significant relationship is not immediately apparent on the

Office of Chief Counsel Division of Corporation Finance February 28, 2013 Page 3

Furthermore, the Response Letters' emphasis on reputational issues is misplaced. With respect to dental amalgams, the Company's customers are typically distributors who in turn sell to dental offices.³ Since, as discussed below, it is the actions of dental offices (not dental manufacturers) and wastewater processors that are the focus of regulatory actions relating to the handling and disposal of waste generated in dental processes, the Company's reputation with these customers is not linked to or affected by the customers' knowledge that the Company manufactures dental amalgam.

The Proposal does not implicate a significant policy issue under Rule 14a-8(i)(7), for two reasons: (1) the Proponents do not provide evidence that there is a widespread public debate regarding dental amalgam; and (2) in any event, the Proposal and its supporting statement focus on concerns that lack a nexus to the Company's activities.

No Widespread Public Debate

Notwithstanding the selective quotations that are included in the Proposal's supporting statement and in the Response Letters, the Proponents simply do not substantiate the existence of a widespread public debate about dental amalgam or its impact on the environment. It is notable that the quotations included in the Response Letters in addition to being selective rather than representative, are drawn almost entirely from bodies and individuals that lack regulatory authority and the accountability that typically accompanies such authority. In addition, while the Second Response Letter has corrected or omitted some of the sweeping assertions contained in the First Response Letter, the Response Letters still attempt to compensate for the lack of public debate regarding dental amalgam by repeatedly conflating the specific topic of dental amalgam with statements regarding mercury in general.

face of the proponent's submission, the proponent, as in the past, could demonstrate the significant relationship supplementally. For example, the proponent could provide information that indicates that while a particular corporate policy which involves an arguably economically insignificant portion of an issuer's business, the policy may have a significant impact on other segments of the issuer's business or subject the issuer to significant contingent liabilities.").

³ Regardless, there is no basis for assuming, as the Response Letters do, that dental patients know who manufactured the amalgam that their dentists use in treating them. With respect to dental offices, who are the primary consumers of and who handle dental amalgam, the Company promotes responsible handling and disposal, as noted on page 5 of the No-Action Request.

Office of Chief Counsel Division of Corporation Finance February 28, 2013 Page 4

Lack of Nexus to Company's Activities

Moreover, the Proposal and its supporting statement focus on concerns (i.e., amalgam disposal and treatment) that lack a nexus to the Company's activities. The Response Letters' attempts to draw a connection between the Company and the handling and disposal techniques of dental offices are predicated on the Second Response Letter's assertion that, "in the opinion of the Proponent a significant part of the mercury in the product will inevitably pollute the environment." Tellingly, the Company's regulators have not drawn a similar conclusion. As the Response Letters concede, the primary regulators of dental amalgam in the United States (the FDA and the EPA) have not found it necessary to restrict the Company's activities with respect to dental amalgam and have not required the Company to eliminate or phase down its amalgam manufacturing. As noted in the No-Action Request, the FDA affirmatively concluded that dental amalgam is effective and safe for adults and children six or older. Moreover, the EPA's actions have been addressed to dental offices and wastewater treatment plants. These EPA actions cast considerable doubt on the assertion on page 7 of the First Response Letter (and a similar assertion on page 6 of the Second Response Letter) that "the use and dissemination in the environment of mercury is inseparable from the production of dental amalgam." Finally, the international organizations and individuals that are quoted in the supporting statement and in the Response Letters likewise have focused primarily on proper handling practices in dental offices.³

⁴ Second Response Letter at pages 2 and 7 (emphasis added).

As noted on pages 9-10 of the First Response Letter and pages 10-11 of the Second Response Letter, while various mercury-containing items were targeted for phase-out at the Minamata Convention on Mercury, dental amalgams were not in this category; rather, dental amalgams are only slated to be phased down in some countries as has already occurred in the U.S. Furthermore, the Response Letters incorrectly characterize the measures of "[s]etting national objectives aiming at minimizing [dental amalgam's] use" and "[p]romoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land" as "binding requirements" under the Minamata Convention. In reality, the treaty lists seven additional measures and requires the signatories to the treaty to enact only "two or more" of the nine measures. Finally, we note that, consistent with our arguments in the No-Action Request and in this letter, one of the two measures that the Response Letters identify relates only to "dental facilities," and the other relates only to "use" of dental amalgam (again, an end-user focus), not to its manufacture. *See* International Institute for Sustainable Development, SUMMARY OF THE FIFTH SESSION OF THE

Office of Chief Counsel Division of Corporation Finance February 28, 2013 Page 5

While we acknowledge that, in some cases, the Staff has concluded that the manufacturer of a product (such as tobacco products) has a nexus to a significant policy issue, that Staff precedent is distinguishable from the present case. Unlike tobacco, dental amalgam is not itself a significant policy issue; amalgam does not itself present a health risk. Rather, the significant policy issue that the Response Letters assert is at stake is an environmental issue that the Response Letters assert results from some end-users' handling of the product. See page 5 of the Response Letters. The Company is not an entity that harms the environment in the manner described in the Proposal because it is not a dental office that disposes of dental amalgams or a wastewater treatment plant that treats amalgam. As a result, the present situation is distinguishable from General Electric Co. (avail. Jan. 17, 2012, recon. denied Mar. 1, 2012) and Citigroup Inc. (avail, Feb. 11, 2009) because the activities targeted by the proposals in those letters-nuclear power generation and predatory lending, respectivelywere themselves significant policy issues in which the companies were allegedly participating. Here, the nexus between the Company and the activities in question is much more tenuous than in General Electric and Citigroup. Because it focuses on a specific item that is not itself a significant policy issue, the Proposal is more akin to Exxon Mobil Corp. (avail. Mar. 6, 2012), in which the Staff concurred in the exclusion of a proposal addressing "risks ... posed by the environmental, social and economic challenges" associated with the company's oil sands operations rather than taking the position that all issues relating to oil sands are inherently environmental. See also Johnson & Johnson (avail. Feb. 22. 2011. recon, denied Mar. 10, 2011 and Apr. 8, 2011) (concurring in the exclusion of a proposal concerning a drug product that allegedly had harmful side effects despite the proposal's assertion that the proposal would promote "the health and happiness of . . . the public").

The Response Letters' "supply chain" analogy also is unavailing in its attempt to construct a nexus between the Proponents' concerns and the Company's activities. In each of the precedents cited in the Response Letters, the proposals were addressing a company's "upstream" suppliers, or (as in *AT&T Inc.* (avail. Feb. 7, 2013)) a company's own use and handling of a material. Unlike in the precedent the Response Letters cite, the Proposal was submitted to the "upstream" Company/manufacturer rather than to a "downstream" company/purchaser. As a manufacturer rather than a purchaser, the Company is not in a position to pressure its customers and end-users in the same way a purchaser can pressure a supplier, as in the precedent cited in the Response Letters. Thus, there is no automatic connection between the Company and amalgam disposal. Instead, as discussed in the No-

INTERGOVERNMENTAL NEGOTIATING COMMITTEE TO PREPARE A GLOBAL LEGALLY BINDING INSTRUMENT ON MERCURY: 13-19 JANUARY 2013, at 8 (Jan. 21, 2013), available at <u>http://www.iisd.ca/download/pdf/enb2822e.pdf</u>. As with the approach of the EPA, the Minamata Convention likewise is not viewing the issue as inherently linked with the manufacture of dental amalgam.

Office of Chief Counsel Division of Corporation Finance February 28, 2013 Page 6

Action Request, the topics that are to be addressed in the report that the Proposal requests – which relate to amalgam production goals, sales data and cost of amalgam alternatives – are far removed from the issue of the downstream disposal and treatment of dental amalgam, and instead implicate numerous aspects of the Company's ordinary business. As demonstrated by the precedent cited in the No-Action Request, even when dealing with a topic that could, in some contexts, implicate a significant policy issue, when a proposal requests a report that has no nexus to the policy issue or that is not limited to the significant policy issue but instead implicates a company's ordinary business operations, that proposal properly may be excluded under Rule 14a-8(i)(7).

Based upon the foregoing analysis and the Company's No-Action Request, we respectfully request that the Staff concur that it will take no action if the Company excludes the Proposal from its 2013 Proxy Materials.

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,

R.M.O. Make

Ronald O. Mueller

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

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SANFORD J. LEWIS, ATTORNEY

February 25, 2013 (revised)

Via email

Office of Chief Counsel 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 – Corrected Reply

Dear Sir/Madam:

Trinity Health, The Benedictine Sisters of Baltimore, The Dominican Sisters of Hope, Providence Trust and Catholic Health East (collectively, the "Proponents") are the beneficial owners of common stock of Danaher Corporation (the "Company") and have submitted a shareholder proposal (the "Proposal") to the Company. We have been asked by the Proponents to respond to the letter dated January 14, 2013, sent to the Securities and Exchange Commission Staff by Ronald O. Mueller on behalf of the Company. In that letter, the Company contends that the Proposal may be excluded from the Company's 2013 proxy statement by virtue of Rule 14a-8(i)(5) and Rule 14a-8(i)(7).

I have reviewed the Proposal, as well as the letter sent by the Company, and based upon the foregoing, as well as the relevant rules, it is my opinion that the Proposal must be included in the Company's 2013 proxy materials and that it is not excludable by virtue of those Rules.

A copy of this letter is being e-mailed concurrently to Ronald O. Mueller.

BACKGROUND

Dentists are by far the largest contributor of mercury to municipal waste water in the US. The dental mercury originates with amalgam that Danaher and other manufacturers sell. The US Environmental Protection Agency (EPA) has made a direct link between amalgam use, and its transformation into one of the most dangerous and toxic forms of mercury, methylmercury. According to a 2010 press release from the US EPA:

"Approximately 50 percent of mercury entering local waste treatment plants comes from dental amalgam waste. Once deposited, certain microorganisms can change elemental mercury into methylmercury, a highly toxic form that builds up in fish, shellfish and animals that eat fish.

PO Box 231 Amherst, MA 01004-0231 • sanfordlewis@strategiccounsel.net 413 549-7333 ph. • 781 207-7895 fax

Methylmercury can damage children's developing brains and nervous systems even before they are born."¹

Mercury has been targeted for reduction by US and international policymakers because it 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.² 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.³

As one of the leading manufacturers of dental amalgam, these pollution issues substantially originate with the manufacture and sale of dental amalgam by Kerr, Inc., a subsidiary of Danaher.

SUMMARY

The Proposal requests that the Company prepare a report on the reduction, leading to eventual elimination, of mercury pollution from dental amalgam, encouraging the Company to become a leader in the global effort to reduce mercury pollution. The full text of the Proposal is included as Attachment A.

The Company asserts that the Proposal may be excluded on the basis of Rule 14a-8(i)(5), and Rule 14a-8(i)(7).

The Proposal may not be excluded on the basis of Rule 14a-8(i)(5) or Rule 14a-8(i)(7). As to Rule 14a-8(i)(5), the Proposal is relevant to a significant segment of the Company, dental products, and therefore is not excludable. In addition to relating to operations in excess of 5% of the company's assets and sales, the Proposal is also "otherwise significantly related" to the company's business due to the high risk of harm to the Company's reputation from association with the serious environmental harms described below.

As to Rule 14a-8(i)(7), the Proposal involves significant social policy issues (environmental pollution) that transcend ordinary business with a nexus to the Company, the Proposal does not micromanage, and therefore the Proposal is not excludable as ordinary business. Because dental amalgam cannot, to the Proponent's knowledge, be produced without substantial mercury content, and because in the opinion of the Proponent a significant part of the mercury in the product will inevitably pollute the environment, the Proposal necessarily focuses on

¹Environmental Protection Agency, "EPA Will Propose Rule to Protect Waterways by Reducing Mercury from Dental Offices / Existing technology is available to capture dental mercury," September 27, 2010 (accessible at <u>http://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/a640db2ebad201cd852577ab00634848!OpenDo</u> cument)

¹U.S. Eavironmental Protection Agency, "Mercury Health Effects, <u>http://www.epa.gov/mercury/effects.htm</u>

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. <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241922/pdf/ehp0112-000562.pdf</u>.

reducing the use of mercury and of dental amalgam. The social policy issue associated with the product is inherent in the product. Accordingly, the proposal is not excludable despite its focus on products of the company.

ANALYSIS

I. The Proposal is relevant to a significant segment of the Company, dental products, and is "otherwise significantly related" to the company's business due to the high risk of negative impact on the Company's reputation, and therefore is not excludable pursuant to Rule 14a-8(i)(5).

Dental amalgam is one of the core products produced by Kerr Inc., a subsidiary of Danaher. Although that company is one of many subsidiaries of Danaher, it is an essential part of the company's dental segment – one of five reportable segments – which according to the Company's 2012 form 10-K, represented 13% of total annual sales in 2011 (Danaher form 10-k, page 4). This is a significant portion of the business under the terms of Rule 14a-8(i)(5), and therefore the Proposal is relevant to the Company.

Furthermore, the Proposal is relevant to that dental segment of the Company, because the issue of dental amalgam pollution is a high-profile issue that may have a significant impact on the reputation of the Company, both its dental segment, and its broader operations.

According to a statement on their website, Danaher's "Dental segment is a leading, worldwide provider of a broad range of equipment, consumables and services."⁴ The Company's subsidiary, Kerr Corporation, is a leading producer of dental amalgam, and, according to the Company's website, "Over the past 120 years, Kerr Corporation has secured a reputation as one of the most trusted names in premiere dental consumables."⁵ The Company's statement about Kerr goes on to say:

The company's business philosophy is simple: Only by listening closely to the customer can we develop the products and strategies that will ensure our place as a market leader. The quality that sets Kerr apart from other manufacturers is our unwavering commitment to innovation. Our breakthroughs in composites, bonding agents, impression materials, cements, and restorative accessories have helped define modern dentistry. Kerr's rich portfolio of product lines and programs reflects our commitment to listening to, understanding, and meeting the needs of our customers.⁶

As news of the pollution impact of dental amalgam becomes apparent to consumers, the "trusted name" of Kerr could be at risk.

⁴ http://www.danaher.com/businesses/dental

⁵ http://www.danaher.com/company/kerr

⁶ http://www.danaher.com/company/kerr

On the "Core Values" section of Danaher's website, the Company makes a number of statements related to customer satisfaction and its corporate reputation. Danaher claims that its "commitment to integrity and our reputation is the foundation for Danaher's success."

A culture of integrity and compliance provides a clear competitive advantage for Danaher. We are committed to building our enterprise with integrity, and we have a reputation for dealing honestly and fairly with our investors, business partners, customers, associates and competitors. Our integrity and compliance motto – Your Integrity: Our Success – says it all.⁷

In a January 2013 Newsletter, the Company's subsidiary Kerr refers to its striving for "constant progress," and its "constant motivation to be even better and more innovative in order to produce more effective products." Kerr states that the developments and innovation that are central its success and corporate philosophy "are usually produced in close collaboration with you, our customers. We always strive, therefore, to remain in close contact with you so that we can take up your suggestions and ideas.⁸ Kerr and its parent company Danaher are both clearly invested in their corporate reputations. Therefore, under the terms of Rule 14a-8(i)(5) this Proposal is "otherwise significantly related" to the Company's business.

Numerous recent proposals that might not have met the numerical thresholds of Rule 14a-8(i)(5) have nevertheless deemed to be non-excludable under the rule because the issues involved had a potential impact on the company's reputation. To cite a few examples: *Devon Energy Corp.* (March 27, 2012) annual report on lobbying; *Gap, Inc.* (March 14, 2012) ending trade partnerships with the government of Sri Lanka until that government ceases human rights violations; *BJ Services Company* (December 10, 2003) land procurement policy that incorporate social and environmental factors; *Halliburton Company* (March 14, 2003) review of company operations in Iran, with reference to financial and reputational risks associated with those activities. In each of these instances, the principal reason why operations that were less than 5% of the company nevertheless met the relevancy test is that there was a reputational connection.

Reputational issues are among the most important ways that an issue can be otherwise significantly related even if the issue related to less than 5% of a company's business. The Staff's longstanding position is that shareholder resolutions implicating ethical, social or public policy issues, as well as matter of public debate, are not subject to the strictures of Rule 14a-8(i)(5). The social concern and reputational linkage of the issue makes this issue "otherwise significantly related" as in *Coach, Inc.* (August 7, 2009), *Wal-mart Stores, Inc.* (March 30, 2010).

Thus, despite Danaher's assertion that dental amalgam amounts to less than 5% of its sales and assets, there is a significant link to its reputation, and especially the reputation

⁷ http://www.danaher.com/integrity-and-compliance

^{* &}quot;Kerr News, Newsletter for Dental Professionals," January 2013, page 3. (http://www.kerrdental.eu/media/595560/kerr_news_1-13english.pdf)

of its dental segment.

2. The Proposal addresses a significant policy issue with a nexus to the Company and therefore is not excludable pursuant to Rule 14a-8(i)(7)

Secondly, the Company asserts that the Proposal is excludable as relating to ordinary business under Rule 14a-8(i)(7). However, the Proposal involves significant social policy issues that transcend ordinary business, and therefore the Proposal is not excludable under Rule 14a-8(i)(7).

While Rule 14a-8(i)(7) permits companies to exclude from their proxy materials shareholder proposals that relate to the company's ordinary business matters, the Commission recognizes that "proposals relating to such matters but focusing on sufficiently significant social policy issues . . . generally would not be considered excludable, because the proposals would transcend the day-to-day business matters and raise policy issues so significant that it would be appropriate for a shareholder vote." Exchange Act Release 34-40018 (May 21, 1998). Notably, "since at least 1990," the SEC Staff "has consistently and uniformly held that shareholder proposals pertaining to **environmental pollution** . . . raise such a significant policy issue that they transcend day-to-day business matters."

The Company in its response consistently refers to regulation by and cases related to the FDA and human health. While environmental pollution obviously has an important impact on human health, the focus of this Proposal is specifically on environmental pollution and dangers to human health posed by environmental pollution. The Proposal does not address any areas in which the FDA is responsible for regulation. Once again, this is an environmental pollution proposal not an FDA human health proposal.

A. Proposals relating to production issues are not excludable as ordinary business where the underlying subject matter giving rise to the proposal is a significant policy issue and there is a clear nexus to the company.

The Company argues that the present Proposal is excludable because it relates to the content of company products which it asserts is a matter of ordinary business for the Company. However, because this is an environmental pollution proposal, the Company's argument fails to lead to exclusion. A proposal can relate to the ordinary business of production decisions yet not be excluded if there is a significant policy issue giving rise to the proposal, a clear nexus to the company and if the proposal does not micromanage. In the present case, all of these elements are present.

There are many instances in which proposals have addressed product content, materials used, the need to innovate and develop alternatives, which have been found to not be excludable as ordinary business. These proposals that have asked manufacturers to change materials, phase out chemicals, where those materials posed a significant policy issue of environmental harm. Examples: *Dow Chemical* (March 7, 2003) requesting a report which included plans to "phase out products and processes leading to admissions of persistent organic pollutants and dioxins,"

Page 6

Baxter International (March 1, 1999) requesting a policy to phase out the production of PVC containing or phthalate-containing medical supplies.

B. A proposal inquiring into the phase down or elimination of an *inherently environmentally harmful* product line is not excludable under the ordinary business exclusion.

Where there is a significant social policy issue that attaches closely to the products and services sold, the fact that the proposal addresses an issue related to products and services does not cause the proposal to be excludable. One sees this phenomenon in numerous proposals which addressed products and services but which were not deemed excludable by the Staff.

For instance, *General Electric* (January 17, 2012, reconsideration denied March 1, 2012) asked the company to phase out its nuclear power related activities and product lines. Even though this relates to the elimination of product lines sold by the Company, because it involved products which many believe to pose a very high risk to the environment with significant controversy and public debate, it was not allowed to be excluded under the ordinary business exclusion.

This is why the present proposal is distinct from other proposals that have been allowed to be excluded on the basis of targeting particular products. In the present instance, the use and dissemination and eventual release into the environment of mercury is inseparable from the production of dental amalgam. Therefore the significant policy issue of environmental pollution causes this proposal to transcend the ordinary business concerns which might otherwise accrue to the focus on a product line.

ITT Corp. (avail. Mar. 12, 2008) a proposal requesting a report on the foreign sales of military and weapons-related products and services by the company was not found to be excludable under Rule 14a-8(i)(7). The supporting statement, quoting the American Red Cross, showed how the proposal presented foreign arms sales as a significant social policy issue: "the greater the availability of arms, the greater the violations of human rights and international humanitarian law." The Staff agreed with the notion that this was a significant policy issue and therefore a great deal of inquiry about products could be made without crossing the line into Rule 14a-8(i)(7) exclusion. The supporting statement of that proposal even asked for the report to include:

- 1) processes used to determine and promote foreign sales;
- 2) criteria for choosing countries with which to do business;

3) a description of procedures used to negotiate foreign arms sales government-togovernment and direct commercial sales and;

4) the percentage of sales for each category and;

5) for the past three years;

(a) categories of military equipment or components including dual-use items, exported with as much statistical information as posssible

(b) categories of contracts for servicing/maintaining equipment

(c) offset agreements for the past three years and

(d) licensing and/or co-production with foreign governments.

So it is clear from this decision that the kind of information which might otherwise relate to ordinary business, does not do so when it is so closely related to a significant policy issue, in this case military and weapons related products and services.

Furthermore, in the middle of the subprime lending crisis, a proposal directed towards ensuring that "nontraditional mortgage loans" were being made consistent with prudent lending practices, even though those loans were clearly a "product" of the company, was also found not excludable under Rule 14a-8(i)(7). Again, a very significant social policy issue was inherent in those loans. Pulte Homes Inc. (Feb. 27, 2008): Proponents requested creation of an independent committee to oversee development and enforcement of policies and procedures ensuring that loan terms and underwriting standards for nontraditional mortgage loans were consistent with prudent lending practices. During the same crisis, an evaluation of Citigroup's loans was also not considered excludable as ordinary business where the subject matter focused on predatory lending its impact on borrowers. Citigroup Inc. (Feb. 11, 2009) The Company argued that determining the marketing, lending and collection procedures for its financial products involved core management decisions not appropriate for shareholder oversight. Unable to argue that predatory lending was not a significant social policy issue, the Company implied that this issue, which was devastating the US economy, was not "highlevel" as compared to global warming, human rights and foreign weapons sales. The Staff found that the Company could not omit the proposal under Rule 14a-8(i)(7). The significant policy issue transcended the fact that this was a focus on products.

See also cases regarding the humane treatment of animals: *Coach Inc.* (August 7, 2009) ending the use of animal fur in company products; Bob Evans Farms (June 6, 2011) encouraging the Board of Directors to *phase in* the use of cage free eggs in its restaurant, found not to be reflective of ordinary business because it focuses on the significant policy issue of humane treatment of animals.

These examples show that a proposal can be directed towards a company's products, as long as those products themselves are inseparable from the significant policy issue that adheres to them. That is also the case in the present matter. Because dental amalgam cannot, to the Proponent's knowledge, be produced without substantial mercury content, and because in the opinion of the Proponent a significant part of the mercury in the product will inevitably pollute the environment, the Proposal necessarily focuses on reducing the use of mercury and of dental amalgam.

C. Proposals relating to supply chains are not excludable as ordinary business where the underlying subject matter giving rise to the proposal is a significant policy issue and there is a clear nexus to the company.

The Company argues that the present Proposal is excludable because it relates to supplier relationships, a matter of ordinary business for the Company. However, because this is an environmental pollution proposal, the Company's argument fails to lead to exclusion. A proposal can relate to the ordinary business of supply chain issues and yet not be excluded if

there is a significant policy issue giving rise to the proposal and a clear nexus to the company. In the present case, both of these are elements are present.

Significant environmental and social policy issues may present overriding and transcendent policy issues that save supply chain proposals from ordinary business exclusion. For example, *Fossil Inc.* (March 5, 2012) requested a report describing the company's supply chain standards related to environmental impacts. In that instance, the company in question was reported to have a growing segment of leather goods. The proposal noted that producing leather goods is a water intensive process and involves discharges of toxic pollution. The company asserted, as Danaher has, that the supply chain and supply-chain standards require business judgments "fundamental to management's ability to control the day-to-day operations of the Company." Further, the company asserted that it delved into a broad spectrum of supply chain issues that were outside the scope of shareholder expertise. However, because the proposal focused primarily on "environmental impacts of the company's operations and does not seek to micromanage the company to such a degree that the exclusion of the proposal would be appropriate" the staff found it was not excludable under Rule 14a-8(i)(7).

Another example, *JM Smucker Inc.* (May 9, 2011), addressed raised the question of how the company's coffee production supply chains posed social and environmental risks, and what the company was doing to control those risks. This proposal was found not excludable under Rule 14a-8(i)(7) because the focus of the proposal was on the significant policy issues of sustainability and human rights.

Also, *Tyson Foods Inc.* (November 25, 2009) related to the use of antibiotics in hog production and throughout the supply chain. Interestingly, this proposal 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 *Tyson Foods Inc.* (December 15, 2009), 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.

Proposals promoting protection of human rights in relation to corporate supply chains have similarly been found non-excludable on ordinary business grounds. For example, numerous companies have faced proposals requesting amendment of corporate policies to adopt and enforce the International Labor Organization Conventions, which address how a company ensures that its supply chain is managed without inflicting human rights abuses. *Family Dollar Stores* (October 23, 2012); *Abercrombie & Fitch and Company* (April 12, 2010). A proposal at *Gap, Inc.* (March 14, 2012) asked the company to end trade partnerships – thus altering its supply chain - with the country of Sri Lanka until the government of that country ceased committing human rights violations, and was found non-excludable on ordinary business claims.

All of these proposals, including the present Proposal, have one thing in common: the companies asserted a lack of control of significant social policy issues in its supply chain, while the proponent successfully asserted that harms "downstream" or "upstream" merited

attention by a company that was well positioned to effect the product supply chain's impacts. This caused the proposals to transcend ordinary business.

In contrast, the precedents cited by the Company are distinguishable from the Proposal in the present case because the subject matter of the cited proposals either did not amount to significant environmental or social policy issues or dealt with product regulatory compliance and product research and development, an area long recognized as "ordinary business" by the Staff. *Applied Digital solutions, Inc.* (avail. Apr. 25, 2006) requested a report on the sale and use of RFID chips, used in a patient identification device regulated by the FDA. The Staff excluded this proposal noting that the proposal related to regulatory compliance issues and compliance determined by the FDA. The *Pfizer Inc.* (avail. Jan. 23, 2006) and *E. I. Du Pont De Nemours and Co.* (avail. Mar. 8,1991) proposals also related to product research, development and testing. The present Proposal does not merely relate to regulatory compliance, product research and development. As discussed above, the Proposal is based on the significant policy issue of environmental harm which is recognized by the Staff as an important policy issue and which, unlike the proposals cited by the company, prevents its exclusion on an ordinary business basis.

D. The issue of dental amalgam environmental pollution is a significant policy issue.

The release of mercury into the environment is an important policy issue. As is evidenced by government reports, international actions, and coverage in the media, the production of dental amalgam fillings plays a key role in this issue.

According to the World Health Organization report *Future Use of Materials for Dental Restoration* (2011), the amount of dental mercury entering the environment is "significant": "A significant amount of mercury is estimated to be released to the environment from the use of dental amalgam either as an indirect result of the diversion of traded amalgam for other purposes or as a result of improper waste management practices or through cremation."

Between 313 and 411 tons of dental mercury is consumed annually, making it one of the largest consumer uses of mercury in the world.¹⁰ The demand for dental mercury is higher than the demand for almost all other mercury products – more than lighting (120-150 tons), measuring devices (300-350 tons), and electrical devices (170-210 tons).¹¹ As other mercury products are being phased out, amalgam is fast becoming the largest source of mercury pollution from products.

¹⁰ 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).

⁹ World Health Organization, FUTURE USE OF MATERIALS FOR DENTAL RESTORATION (2011), page 13. (accessible at <u>http://www.who.int/oral_health/publications/dental_material_2011.pdf</u>)

¹¹ UNEP, Mercury-Containing Products Partnership Area Business Plan (2011) (accessible at http://www.unep.org/hazardoussubstances/Mercury/InterimActivities/Partnerships/Products/tabid/ 3565/language/en-US/Default.aspx).

The environmental risks posed by the release of mercury into the environment were addressed in a 2012 European Commission study on the potential for reducing mercury pollution. In the section titled, "Environmental aspects of dental amalgam use," the report states:

There are also environmental risks, for example the disturbance of microbiological activity in soils and harm to wildlife populations. The effects of mercury releases on the integrity of the ecosystem are substantial. Various species – especially eagles, loons, kingfishers, ospreys, ibises, river otters, mink and others that rely on fish for a large part of their diet – have been observed to suffer adverse health and/or behavioural effects. Observed disorders such as effects on the muscles and nervous system, reduced or altered mating habits, ability to reproduce, raise offspring, catch food and avoid predators have been demonstrated to affect individual animal viability and overall population stability.¹²

In the 2011 WHO report¹³ the issue of amalgam manufacturers is addressed. Under the heading "Manufacturers", the report states: "The dental industry must adapt to a future situation of lower use of dental amalgam and higher use of materials alternative to amalgam. Improving the quality and affordability of dental restorative materials are the social responsibilities of the dental industry. In order for dental care to be financially fair, prices on alternative materials must be reduced. It is a vital role of the dental manufacturers to ensure supply and distribution of materials for restorative dental care in all countries." (pages 36-37). While recommending the phase-down of amalgam, the WHO report explains that "Manufacturers have an important part to play in ensuring that the materials are readily accessible, easy to use and costeffective." (page 20).

On January 19, 2013, delegates representing more than 140 countries approved the text for a legally binding treaty on mercury, the Minamata Convention on Mercury.¹⁴ The proposed treaty -- which is scheduled to be signed by the government ministers at a ceremony in Minamata, Japan, in October 2013, includes binding requirements for countries to phase down the use of dental amalgam. Specifically, the final text includes: item (ii) Setting national objectives aiming at minimizing its use; and item (ix) Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.¹⁵ The United Nations

http://ec.europa.eu/environment/chemicals/mercury/pdf/Final_report_11.07.12.pdf).

¹² European Commission, Study on the potential for reducing mercury pollution from dental amalgam and batteries," July 11, 2012 (accessible at

¹³ World Health Organization, FUTURE USE OF MATERIALS FOR DENTAL RESTORATION (2011). (accessible at <u>http://www.who.int/oral_health/publications/dental_material_2011.pdf</u>)

¹⁴ http://www.unep.org/hazardoussubstances/Mercury/Negotiations/INC5/tabid/3471/Default.aspx

¹⁵ New UN treaty on mercury will require countries to reduce and eliminate most mercury uses, and phase down dental amalgam (accessible at

http://www.unep.org/hazardoussubstances/Mercury/Negotiations/INC5/tabid/3471/Default.aspx:a summary of the discussions is available at: http://www.iisd.ca/mercury/inc5/))

Environment Programme (UNEP) News Centre article quotes Achim Steiner, UN Under-Secretary General and Executive Director of UNEP which convened the negotiations, said at the close: "After complex and often all night sessions here in Geneva, nations have today laid the foundations for a global response to a pollutant whose notoriety has been recognized for well over a century."¹⁶ Environment ministers at the 2009 session of the UNEP Governing Council decided to launch negotiations on mercury. The Geneva session, which approved the treaty, was the final and fifth negotiation.

Also on January 22, 2013, an article quoted Troy Williams, ADIA Chief Executive Officer, Australian Dental Industry Association indicated: "There was widespread acceptance that dental amalgam is a major source of mercury pollution, particularly in waterways. In this context, the dental industry is supportive of moves towards alternative restorative materials."¹⁷

The UNEP-WHO amalgam "phase down" project is being conducted in collaboration with the World Dental Federation, FDI (of which Kerr is a member the American Dental Association is a member) which believes the project to be a step in the right direction, described through the lens of industry.¹⁸

The British Dental Association, which represented FDI (the world dental trade association, of which the ADA is a member): The latest release from the FDI treaty representative reaffirms an earlier statement where they welcome amalgam phase down for environmental reasons.¹⁹

On January 23, 2013, the International Dental Tribune covered the treaty story.²⁰ According to the article,

The American Dental Association has announced that it is very satisfied with the results of the recent UN meeting on reducing and eliminating mercury release and exposure. The delegates agreed on binding requirements for countries to phase down dental amalgam, among other resolutions.

"We also recognize that we do have a responsibility to the environment," Daniel M. Meyer, DDS, senior vice president for science/professional affairs at the American Dental

¹⁶ Minamata Convention Agreed by Nations (accessible at

http://www.unep.org/newscentre/Default.aspx?DocumentID=2702&ArticleID=9373&l=en) ¹⁷ Australian Dental Industry Association (accessible at

http://www.oralhealthgroup.com/news/un-convetion-confirms-phased-down-approach-for-dentalamalgam/1002002705/)

¹⁸ UNEP-WHO Project (accessible at

http://www.fdiworldental.org/fdi-at-work/programme-for-africa/unep-dental-amalgam-phase-do wnproject.aspx)

¹⁹ British Dental Association, representing the FDI, the world dental trade association (accessible at <u>http://www.dentistry.co.uk/news/dentists-welcome-%E2%80%98phase-down%E2%80%99-mercury-treaty</u>)

²⁰ The International Dental Tribune (accessible at

http://www.dental-

tribune.com/articles/news/americas/11498_ada_welcomes_un_treaty_on_global_mercury_ph asedown.html)

Association, told *Medscape Medical News*. "The House of Delegates passed a resolution to work with the [Environmental Protection Agency] to establish appropriate regulations."²¹

In Nairobi on December 19, 2012, during the inception workshop²² for the East Africa WHO-UNEP Amalgam Phase Down project, which includes industry, **Case studies demonstrating amalgam phase-down approach: Initial findings**, a power point created by Mercury Policy Project/Tides Center was presented by UNEP staff.²³

In anticipation of this treaty, the issue of mercury toxicity, including from dental amalgam fillings, received national coverage in *The New York Times* in December 2012.²⁴ The UN mercury treaty follows in line with actions already taken by a number of countries. Indeed, Japan and Finland have implemented measures to greatly reduce the production and use of dental amalgams containing mercury,²⁵ and Norway, Sweden, and Denmark have virtually phased out its use via legal restrictions and prohibitions.²⁶ A 2012 report for the European Commission (EC) recommended phasing out amalgam in five years.²⁷

D. The subject matter has a clear nexus to the Company.

The Company is one of very few companies that drive production of dental amalgam. Its decisions regarding whether to produce, or phase out, dental amalgam will have an enormous impact on the flow of dental amalgam into the environment. In a UNEP list of manufacturers, Kerr is one of very few companies listed as manufacturing amalgam.²⁸²⁹As a recent report explained: "The business of developing and marketing mercuryfree filling materials is high-tech, innovative, and spread among many more companies than the handful that market amalgam. Any move that further encourages mercury-free materials will also encourage investment, R&D, marketing and related commercial activities – not to mention increased exports – well beyond any that might

http://ec.europa.eu/environment/chemicals/mercury/pdf/Final_report_11.07.12.pdf).

²⁸http://www.unep.org/hazardoussubstances/Mercury/PrioritiesforAction/Products/Reports/tabid/4513/lang uage/en-US/Default.aspx.

²¹ American Dental Association re Environmental Protection Agency (accessible at http://www.medscape.com/viewarticle/778273

²²<u>http://www.unep.org/hazardoussubstances/Mercury/PrioritiesforAction/Products/Activities/EastAfricaDentalAmalgamPhase-DownProject/tabid/105844/Default.aspx</u>

²³ http://mercurypolicy.org/wp-

content/uploads/2013/01/case_studies_amalgam_phase_down_mpp_final.pdf

²⁴ "If Mercury Pollution Knows No Borders, Neither Can Its Solution," Kate Galbraith, New York Times, December 12, 2012 (http://www.nytimes.com/2012/12/13/business/energy-environment/ifmercury-pollution-knows-no-borders-neither-can-its-solution.html?_r=0)

²⁵ United Nations Environmental Programme & Arctic Monitoring and Assessment Programme Report, "Technical Background Report to the Global Atmospheric Mercury Assessment," page 10. (accessible at

http://www.chem.unep.ch/mercury/Atmospheric_Emissions/Technical_background_report.pdf).

²⁶ Reuters, "Dental Mercury Use Banned in Norway, Sweden and Denmark because Composites are Adequate ...," January 3, 2008 (http://www.reuters.com/article/2008/01/03/idUS108558+03-Jan-2008+PRN20080103).

²⁷ European Commission, Study on the potential for reducing mercury pollution from dental amalgam and batteries," July 11, 2012 (accessible at

take place among the staid amalgam producers. The overall benefits in this case, including increased competition and a steadily decreasing price for the product, are difficult to calculate with any precision, but they are clearly significant."³⁰

As demonstrated by the recent Staff decision in AT&T (February 7, 2013) and many other cases cited above, the fact that a company does not do business at the point at which materials are released to the environment does not prevent a nexus from applying. In the AT&T example, the proposal ask the Company to report on its methods of ensuring that batteries used in its data centers are not polluting the environment at the point of production or disposal. The Company had argued that what happened at those upstream and downstream locations in the supply chain did not have a nexus to the Company. The Proponent argued that the Company was well situated to address the issue of the environmental impacts of its activities, because of the volume of its usage of the batteries. The Staff found that the Proposal was not excludable under the ordinary business exclusion.

Similarly, in the present instance, the Company is very well situated to drive markets towards less mercury bearing dental amalgam. If it were to declare that it intends to phase out the use of mercury in dental amalgam, it would help to drive the market toward the less polluting options for fillings.

E. The Proposal does not micromanage the Company's business.

The requests of the Proposal are at a similar level of detail to many other proposals requesting reports from companies, which have not been found to micromanage or otherwise be excludable under Rule 14a-8(i)(7). See for instance, *Chesapeake Energy* (April 2, 2010) in which the proposal requested a report summarizing 1 the environmental impact of fracturing operations of Chesapeake Energy Corporation; 2. potential policies for the company to adopt, above and beyond regulatory requirements, to reduce or eliminate hazards to air, water, and soil quality from fracturing; 3. other information regarding the scale, likelihood and/or impacts of potential material risks, short or long-term to the company's finances or operations, due to environmental concerns regarding fracturing. In its supporting statement, the proposal went on to describe additional items that should be disclosed including, among other things, use of less toxic fracturing fluids, recycling or reuse of waste fluids, and other structural or procedural strategies to reduce fracturing hazards.

CONCLUSION

As demonstrated above, the Proposal is not excludable under the asserted rules. Therefore, we request the Staff to inform the Company that the SEC proxy rules require denial of the Company's no-action request. In the event that the Staff should decide to concur with the Company, we respectfully request an opportunity to confer with the Staff.

³⁰ Concorde East/West, The Real Cost of Dental Mercury (2012), http://www.toxicteeth.org/CMSTemplates/ToxicTeeth/pdf/The-Real-Cost-of-Dental-Mercury-final.aspx

Please call Sanford Lewis at (413) 549-7333 with respect to any questions in connection with this matter, or if the Staff wishes any further information.

Sincerely

Sanford Lewis Attorney at Law

cc: Ronald O. Mueller, Gibson Dunn Valerie Heinonen, Dominican Sisters of Hope Catherine M. Rowan, Trinity Health Kathleen Coll, Catholic Health East Dianne Heinrich, Providence Trust Kathleen White, Benedictine Sisters of Baltimore Page 14

Page 15

APPENDIX A

PROPOSAL

Whereas:

Dental amalgam is composed of approximately 50% mercury, a reproductive and neurological toxicant. Mercury is a concern when it enters the environment through uncontrolled releases via dental office wastes, fecal matter, breathing, burial, and cremation.¹ Mercury can be transformed into methylmercury, which bioaccumulates and can adversely affect the nervous system of those who consume fish.²

At the 25th session of the Governing Council of the UN Environment Programme in 2009, more than 120 nations agreed to work toward legally binding measures to control mercury pollution and created an Intergovernmental Negotiating Committee (INC). Since then four INCs have been held in: Sweden, Japan, Kenya and Uruguay.³

In 2011, the World Health Organization released an expert group report⁴, which stated that amalgam poses a serious environmental health problem because it releases a "significant amount of mercury" into the environment, including atmosphere, surface water, groundwater, and soil. It affirmed: "When released from dental amalgam use into the environment through these pathways, mercury is transported globally and deposited. Mercury releases may then enter the human food chain especially via fish consumption."

The WHO report recommends "a switch in use of dental materials"⁵ away from amalgam, explaining "for many reasons restorative materials alternative to dental amalgam are desirable" and commits itself, urging all health agencies to join them, to "work for reduction of mercury and the development of a healthy environment." To accomplish this goal, "WHO will facilitate the work for a switch in use of dental materials."

DANAHER reports quantities of mercury contained in products sold in the U.S. Product manufacturers submit such information in compliance with 8 state laws in effect since January 2001. Statistics appear to indicate that DANAHER reported a 57% decline in total quantity of mercury used for dental amalgams between 2007 and 2010.

RESOLVED: Shareholders request that the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, by October 31, 2013 summarizing DANAHER's policies and plans for eliminating releases into the environment of mercury from DANAHER products.

Supporting Statement

Shareholders believe such report should include DANAHER's: (i) goals for reduction in its production of dental amalgam and associated reductions in mercury use; (ii) annual production and sales on usage of mercury in amalgam globally for the prior year; (iii) projected reduction in usage of mercury for each of the next four years; (iv) by what date, if any, DANAHER projects it will cease production of amalgam and (v) what DANAHER is doing to reduce costs of alternatives to dental amalgams.

¹ http://mpp.cclearn.org/wp-content/uploads/2008/08/benders-testimony.pdf

² www.epa.gov/ost/criteria/methylmercury/factsheet.html

³ http://www.unep.org/hazardoussubstances/Mercury/Negotiations/tabid/3320/Default.aspx

⁴ http://www.who.int/oral_health/publications/dental_material_2011.pdf

⁵ http://newmoa.org/prevention/mercury/imerc/notification/browsecompany.cfm?pid=92

SANFORD J. LEWIS, ATTORNEY

February 15, 2013

Via email to shareholderproposals@sec.gov

Office of Chief Counsel 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

Ladies and Gentlemen:

Trinity Health, The Benedictine Sisters of Baltimore, The Dominican Sisters of Hope, Providence Trust and Catholic Health East (collectively, the "Proponents") are the beneficial owners of common stock of Danaher Corporation (the "Company") and have submitted a shareholder proposal (the "Proposal") to the Company. We have been asked by the Proponents to respond to the letter dated January 14, 2013, sent to the Securities and Exchange Commission Staff by the Company. In that letter, the Company contends that the Proposal may be excluded from the Company's 2013 proxy statement by virtue of Rule 14a-8(i)(5) and Rule 14a-8(i)(7).

I have reviewed the Proposal, as well as the letter sent by the Company, and based upon the foregoing, as well as the relevant rules, it is my opinion that the Proposal must be included in the Company's 2013 proxy materials and that it is not excludable by virtue of those Rules.

A copy of this letter is being e-mailed concurrently to Ronald O. Mueller (on behalf of Gibson, Dunn, & Crutcher LLP) and the Proponents.

BACKGROUND

Dentists are one of the largest users of mercury¹ and by far the largest contributor of mercury to municipal waste water in the US today. The mercury originates with amalgam that Danaher and other manufacturers sell both into the US market and globally. The US Environmental Protection Agency (EPA) has made a direct link between amalgam use, and its transformation into one of the most dangerous and toxic forms of mercury, methylmercury. According to a 2010 press release from the US EPA:

¹ IMERC Data Base and Fact Sheet Mercury Use in Dental Amalgam Last Update: June 2010 (assessed at: <u>http://www.newmoa.org/prevention/mercury/imerc/factsheets/dental_amalgam.cfm</u> and http://www.newmoa.org/prevention/mercury/imerc.cfm)

Danaher – Proposal on Environmental Impact of Dental Amalgam Proponent Response – February 15, 2013

> "Approximately 50 percent of mercury entering local waste treatment plants comes from dental amalgam waste. Once deposited, 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."²

Mercury has been targeted for reduction and elimination by US and international policymakers because it 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.³ Based upon blood sampling data, federal scientists previously 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.⁴ As one of the leading manufacturers of dental amalgam, these mercury pollution issues originate with the manufacture and sale of dental amalgam by Kerr, Inc., a subsidiary of Danaher.

SUMMARY

The Proposal requests that the Company prepare a report on elimination of mercury pollution by reducing the sales of amalgam containing mercury. The full text of the Proposal is included as Attachment A.

The Company asserts that the Proposal may not be excluded on the basis of Rule 14a-8(i)(5) or Rule 14a-8(i)(7).

As to Rule 14a-8(i)(5), the Proposal is relevant to a significant segment of the Company, dental products (13% of sales), and therefore is not excludable. In addition to relating to operations in excess of 5% of the company's assets and sales, the Proposal is also "otherwise significantly related" to the company's business due to the high risk of harm to the Company's reputation from association with the serious environmental harms described below.

²Environmental Protection Agency, "EPA Will Propose Rule to Protect Waterways by Reducing Mercury from Dental Offices / Existing technology is available to capture dental mercury," September 27, 2010 (accessible at

http://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/a640db2ebad201cd85 2577ab00634848!OpenDocument)

³ U.S. Environmental Protection Agency, "Mercury Health Effects, http://www.epa.gov/mercury/effects.htm

⁴ Mahaffey et al., Blood Organic Mercury and Dietary Mercury Intake: National Health and Nutrition Examination Survey, 1999 and 2000, Environmental Health Perspectives, April 2004. <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241922/pdf/ehp0112-000562.pdf</u>.

As to Rule 14a-8(i)(7), the Proposal involves significant social policy issues that transcend ordinary business, and therefore the Proposal is not excludable as ordinary business.

ANALYSIS

1. The Proposal is relevant to a significant segment of the Company, dental products, and therefore is not excludable pursuant to Rule 14a-8(i)(5)

The Company asserts that the Proposal is excludable under Rule 14a-8(i)(5):

(5) *Relevance:* If the proposal relates to operations which account for less than 5 percent of the company's total assets at the end of its most recent fiscal year, and for less than 5 percent of its net earnings and gross sales for its most recent fiscal year, and is not otherwise significantly related to the company's business;

In this instance, the Proposal is not excludable both because it relates to operations in excess of 5% of the company's assets and sales, and also because it is "otherwise significantly related" to the company's business.

Dental amalgam is one of the core products produced by Kerr Inc., a subsidiary of Danaher. Although that company is one of many subsidiaries of Danaher, it is an essential part of the company's dental segment – one of five reportable segments – which according to the Company's 2012 form 10-K, represented 13% of total annual sales in 2011 (Danaher form 10-k, page 4). This is a significant portion of the business under the terms of Rule 14a-8(i)(5), and therefore the Proposal is relevant to the Company.

Furthermore, the Proposal is relevant to that dental segment of the Company, because the issue of dental amalgam pollution is a high-profile issue that may have a significant impact on the reputation of the Company, both its dental segment, and its broader operations.

According to a statement on their website, Danaher's "Dental segment is a leading, worldwide provider of a broad range of equipment, consumables and services."⁵ The Company's subsidiary, Kerr Corporation, is a leading producer of dental amalgam, and, according to the Company's website, "Over the past 120 years, Kerr Corporation has secured a reputation as one of the most trusted names in premiere dental consumables."⁶ The Company's statement about Kerr goes on to say:

The company's business philosophy is simple: Only by listening closely to the customer can we develop the products and strategies that will ensure our place as a market leader. The quality that sets Kerr apart from other

⁵ http://www.danaher.com/businesses/dental

⁶ http://www.danaher.com/company/kerr

manufacturers is our unwavering commitment to innovation. Our breakthroughs in composites, bonding agents, impression materials, cements, and restorative accessories have helped define modern dentistry. Kerr's rich portfolio of product lines and programs reflects our commitment to listening to, understanding, and meeting the needs of our customers.⁷

It appears most apparent that as news of the mercury pollution impact of dental amalgam becomes apparent to consumers, the "trusted name" of Kerr could be at risk. On the "Core Values" section of Danaher's website, the Company makes a number of statements related to customer satisfaction and its corporate reputation. Danaher claims that its "commitment to integrity and our reputation is the foundation for Danaher's success."

A culture of integrity and compliance provides a clear competitive advantage for Danaher. We are committed to building our enterprise with integrity, and we have a reputation for dealing honestly and fairly with our investors, business partners, customers, associates and competitors. Our integrity and compliance motto – Your Integrity: Our Success – says it all.⁸

In a January 2013 Newsletter, the Company's subsidiary Kerr refers to its striving for "constant progress," and its "constant motivation to be even better and more innovative in order to produce more effective products." Kerr states that the developments and innovation that are central its success and corporate philosophy "are usually produced in close collaboration with you, our customers. We always strive, therefore, to remain in close contact with you so that we can take up your suggestions and ideas.⁹ Kerr and its parent company Danaher are both clearly invested in their corporate reputations. Therefore, under the terms of Rule 14a-8(i)(5) this Proposal is "otherwise significantly related" to the Company's business.

Reputational issues are among the most important ways that an issue can be otherwise significantly related even if the issue related to less than 5% of a company's business. The Staff's longstanding position is that shareholder resolutions implicating ethical, social or public policy issues, as well as matter of public debate, are not subject to the strictures of Rule 14a-8(i)(5). The social concern and reputational linkage of the issue makes this issue "otherwise significantly related". *Coach, Inc.* (August 7, 2009), *Walmart* Stores, Inc. (March 30, 2010).

Numerous other instances in recent years have involved proposals which might not have met the numerical thresholds of Rule 14a-8(i)(5), but which were nevertheless deemed to be non-excludable under the rule because the issues involved had a potential impact on the company's reputation. To cite a few examples: *Devon Energy Corp.* (March 27, 2012) annual report on lobbying; *Gap, Inc.* (March 14, 2012) ending trade partnerships with the

⁷ http://www.danaher.com/company/kerr

⁸ http://www.danaher.com/integrity-and-compliance

⁹ "Kerr News, Newsletter for Dental Professionals," January 2013, page 3.

⁽http://www.kerrdental.eu/media/595560/kerr_news_1-13english.pdf)

government of Sri Lanka until that government ceases human rights violations; BJ Services Company (December 10, 2003) land procurement policy that incorporate social and environmental factors; Halliburton Co.(March 14, 2003) review of company operations in Iran, with reference to financial and reputational risks associated with those activities. In each of these instances, principal reason why operations that were less than 5% of the company nevertheless met the relevancy test is that there was a reputational connection.

Thus, despite Danaher's assertion that dental amalgam amounts to less than 5% of its sales and assets, there is a significant link to its reputation, and especially the reputation of its dental segment.

2. The Proposal addresses a significant policy issue with a nexus to the Company and therefore is not excludable pursuant to Rule 14a-8(i)(7)

Secondly, the Company asserts that the Proposal is excludable as relating to ordinary business under Rule 14a-8(i)(7). However, the Proposal involves significant social policy issues that transcend ordinary business, and therefore the Proposal is not excludable under Rule 14a-8(i)(7).

While Rule 14a-8(i)(7) permits companies to exclude from their proxy materials shareholder proposals that relate to the company's ordinary business matters, the Commission recognizes that "proposals relating to such matters but focusing on sufficiently significant social policy issues . . . generally would not be considered excludable, because the proposals would transcend the day-to-day business matters and raise policy issues so significant that it would be appropriate for a shareholder vote." Exchange Act Release 34-40018 (May 21, 1998). Notably, "since at least 1990," the SEC Staff "has consistently and uniformly held that shareholder proposals pertaining to **environmental pollution** . . . raise such a significant policy issue that they transcend day-to-day business matters."

The Company in its response consistently refers to regulation by and cases related to the FDA and human health. While environmental pollution obviously has an important impact on human health, the focus of this Proposal is specifically on environmental pollution and dangers to human health posed by environmental pollution. The Proposal does not address any areas in which the FDA is responsible for regulation. Once again, this is an environmental pollution proposal not an FDA human health proposal. The resolve clause and whereas clauses make it very clear that this is an environmental proposal, not a consumer health proposal.

A. Proposals relating to supply chains are not excludable as ordinary business where the underlying subject matter giving rise to the proposal is a significant policy issue and there is a clear nexus to the company.

The Company argues that the present Proposal is excludable because it relates to supplier relationships, a matter of ordinary business for the Company. However, because this is an

environmental pollution proposal, the Company's argument fails to lead to exclusion. A proposal can relate to the ordinary business of supply chain issues and yet not be excluded if there is a significant policy issue giving rise to the proposal and a clear nexus to the company. In the present case, both of these are elements are present.

Significant environmental and social policy issues may present overriding and transcendent policy issues that save supply chain proposals from ordinary business exclusion. For example, *Fossil Inc.* (March 5, 2012) requested a report describing the company's supply chain standards related to environmental impacts. In that instance, the company in question was reported to have a growing segment of leather goods. The proposal noted that producing leather goods is a water intensive process and involves discharges of toxic pollution. The company asserted, as Danaher has, that the supply chain and supply-chain standards require business judgments "fundamental to management's ability to control the day-to-day operations of the Company." Further, the company asserted that it delved into a broad spectrum of supply chain issues that were outside the scope of shareholder expertise. However, because the proposal focused primarily on "environmental impacts of the company's operations and does not seek to micromanage the company to such a degree that the exclusion of the proposal would be appropriate" the staff found it was not excludable under Rule 14a-8(i)(7).

Another example, *JM Smucker Inc.* (May 9, 2011), raised the question of how the company's coffee production supply chains posed social and environmental risks, and what the company was doing to control those risks. This proposal was found not excludable under Rule 14a-8(i)(7) because the focus of the proposal was on the significant policy issues of sustainability and human rights.

Also, *Tyson Foods Inc.* (November 25, 2009) related to the use of antibiotics in hog production and throughout the supply chain. Interestingly, this proposal 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 *Tyson Foods Inc.* (December 15, 2009), 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.

Proposals promoting protection of human rights in relation to corporate supply chains have similarly been found non-excludable on ordinary business grounds. For example, numerous companies have faced proposals requesting amendment of corporate policies to adopt and enforce the International Labor Organization Conventions, which address how a company ensures that its supply chain is managed without inflicting human rights abuses. *Family Dollar Stores* (October 23, 2012); *Abercrombie & Fitch and Company* (April 12, 2010). A proposal at *Gap, Inc.* (March 14, 2012) asked the company to end trade partnerships – thus altering its supply chain - with the country of Sri Lanka until the government of that country ceased committing human rights violations, and was found non-excludable on ordinary business claims.

All of these proposals, including the present Proposal, have one thing in common: they assert that the lack of legal control or enforcement adequate to protect against serious environmental harm and/or human rights abuses "downstream" in the supply chain merits a shift in responsibility "upstream", to the companies that produce the products, create the contracts and are well positioned to manage the product supply chain.

In contrast, the precedents cited by the Company are distinguishable from the Proposal in the present case because the subject matter of the cited proposals either did not amount to significant environmental or social policy issues or dealt with product regulatory compliance and product research and development, an area long recognized as "ordinary business" by the Staff. *Applied Digital solutions, Inc.* (avail. Apr. 25, 2006) requested a report on the sale and use of RFID chips, used in a patient identification device regulated by the FDA. The Staff excluded this proposal noting that the proposal related to regulatory compliance issues and compliance determined by the FDA. The *Pfizer Inc.* (avail. Jan. 23, 2006) and *E. I. Du Pont De Nemours and Co.* (avail. Mar. 8,1991) proposals also related to product research, development and testing. The present Proposal does not relate to regulatory compliance, product research and development. As discussed above, the Proposal is based on the significant policy issue of environmental harm which is recognized by the Staff as an important policy issue and which, unlike the proposals cited by the company, prevents its exclusion on an ordinary business basis.

A proposal inquiring into the phase down or elimination of an inherently environmentally harmful product line is not excludable under the ordinary business exclusion.

In the current proposal's inquiry into elimination of a harmful activity by the Company which happens to also involves one of its products which is inherently harmful to the environment, the proposal is consistent with other proposals relating to nuclear power which have not been allowed to be excluded. For instance, *General Electric* (January 17, 2012, reconsideration denied March 1, 2012) asked the company to phase out its nuclear power related activities and product lines. Even though this relate to the elimination of product lines sold by the Company, because it involved a products which many believe to pose a very high risk to the environment with significant controversy and public debate, it was not allowed to be excluded under the ordinary business exclusion. This is why the present proposal is distinct from other proposals which have been allowed to be excluded on the basis of targeting particular products. In the present instance, the use and dissemination in the environment of mercury is inseparable from the production of dental amalgam. Therefore the significant policy issue of environmental pollution causes this proposal to transcend the ordinary business concerns which might otherwise accrue to the focus on a product line.

The Proposal does not micromanage the Company's business.

The requests of the Proposal are at a similar level of detail to many other proposals requesting reports from companies, which have not been found to micromanage or otherwise be excludable under Rule 14a-8(i)(7). See for instance, *Chesapeake Energy* (April 2, 2010) in which the proposal requested a report summarizing 1.the environmental impact of fracturing operations of Chesapeake Energy Corporation; 2. potential policies for the company to adopt, above and beyond regulatory requirements, to reduce or eliminate hazards to air, water, and

soil quality from fracturing; 3. other information regarding the scale, likelihood and/or impacts of potential material risks, short or long-term to the company's finances or operations, due to environmental concerns regarding fracturing. In its supporting statement, the proposal went on to describe additional items that should be disclosed including, among other things, use of less toxic fracturing fluids, recycling or reuse of waste fluids, and other structural or procedural strategies to reduce fracturing hazards.

The issue of dental amalgam environmental pollution is a significant policy issue.

The release of mercury into the environment is an important policy issue. As is evidenced by government reports, international actions, and coverage in the media, the production of dental amalgam fillings plays a key role in this issue.

According to the World Health Organization report *Future Use of Materials for Dental Restoration* (2011), the amount of dental mercury entering the environment is "significant": "A significant amount of mercury is estimated to be released to the environment from the use of dental amalgam either as an indirect result of the diversion of traded amalgam for other purposes or as a result of improper waste management practices or through cremation."¹⁰

Between 313 and 411 tons of dental mercury is consumed annually, making it one of the largest consumer uses of mercury in the world.¹¹ The demand for dental mercury is higher than the demand for almost all other mercury products – more than lighting (120-150 tons), measuring devices (300-350 tons), and electrical devices (170-210 tons).¹² As other mercury products are being phased out, amalgam is fast becoming the largest source of mercury pollution from products.

The environmental risks posed by the release of mercury into the environment were addressed in a 2012 European Commission study on the potential for reducing mercury pollution. In the section titled, "Environmental aspects of dental amalgam use," the report states:

There are also environmental risks, for example the disturbance of microbiological activity in soils and harm to wildlife populations. The effects of mercury releases on the integrity of the ecosystem are substantial. Various species – especially eagles, loons, kingfishers, ospreys, ibises, river otters, mink and others that rely on fish for a large part of their diet – have been observed to suffer adverse health and/or behavioural effects. Observed disorders such as effects on the muscles and nervous system, reduced or

¹⁰ World Health Organization, FUTURE USE OF MATERIALS FOR DENTAL RESTORATION (2011), page 13. (accessible at http://www.who.int/oral_health/publications/dental_material_2011.pdf)

¹¹ 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).

¹² UNEP, Mercury-Containing Products Partnership Area Business Plan (2011) (accessible at http://www.unep.org/hazardoussubstances/Mercury/InterimActivities/Partnerships/Products/tabid/ 3565/language/en-US/Default.aspx).

altered mating habits, ability to reproduce, raise offspring, catch food and avoid predators have been demonstrated to affect individual animal viability and overall population stability.¹³

In the 2011 WHO report¹⁴ the issue of amalgam manufacturers is addressed. Under the heading "Manufacturers", the report states: "The dental industry must adapt to a future situation of lower use of dental amalgam and higher use of materials alternative to amalgam. Improving the quality and affordability of dental restorative materials are the social responsibilities of the dental industry. In order for dental care to be financially fair, prices on alternative materials must be reduced. It is a vital role of the dental manufacturers to ensure supply and distribution of materials for restorative dental care in all countries." (pages 36-37). While recommending the phase-down of amalgam, the WHO report explains that "Manufacturers have an important part to play in ensuring that the materials are readily accessible, easy to use and costeffective." (page 20).

On January 19, 2013, delegates representing more than 140 countries approved the text for a legally binding treaty on mercury, the Minamata Convention on Mercury.¹⁵ The proposed treaty -- which is scheduled to be signed by the government ministers at a ceremony in Minamata, Japan, in October 2013, includes binding requirements for countries to phase down the use of dental amalgam. Specifically, the final text includes: item (ii) Setting national objectives aiming at minimizing its use; and item (ix) Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.¹⁶ The United Nations Environment Programme (UNEP) News Centre article quotes Achim Steiner, UN Under-Secretary General and Executive Director of UNEP which convened the negotiations, said at the close: "After complex and often all night sessions here in Geneva, nations have today laid the foundations for a global response to a pollutant whose notoriety has been recognized for well over a century."¹⁷ Environment ministers at the 2009 session of the UNEP Governing Council decided to launch negotiations on mercury. The Geneva session, which approved the treaty, was the final and fifth negotiation.

¹⁷ Minamata Convention Agreed by Nations (accessible at http://www.unep.org/newscentre/Default.aspx?DocumentID=2702&ArticleID=9373&l=en)

¹³ European Commission, Study on the potential for reducing mercury pollution from dental amalgam and batteries," July 11, 2012 (accessible at

http://ec.europa.eu/environment/chemicals/mercury/pdf/Final_report_11.07.12.pdf).

¹⁴ World Health Organization, FUTURE USE OF MATERIALS FOR DENTAL RESTORATION (2011). (accessible at http://www.who.int/oral_health/publications/dental_material_2011.pdf)

¹⁵ http://www.unep.org/hazardoussubstances/Mercury/Negotiations/INC5/tabid/3471/Default.aspx

¹⁶ New UN treaty on mercury will require countries to reduce and eliminate most mercury uses, and phase down dental amalgam (accessible at

http://www.unep.org/hazardoussubstances/Mercury/Negotiations/INC5/tabid/3471/Default.aspx;a summary of the discussions is available at: http://www.iisd.ca/mercury/inc5/))

Also on January 22, 2013 an article quoted Troy Williams, ADIA Chief Executive Officer, Australian Dental Industry Association indicated: "There was widespread acceptance that dental amalgam is a major source of mercury pollution, particularly in waterways. In this context, the dental industry is supportive of moves towards alternative restorative materials." ¹⁸

The UNEP-WHO amalgam "phase down" project is being conducted in collaboration with the World Dental Federation, FDI (of which Kerr is a member the American Dental Association is a member) which believes the project to be a step in the right direction, described through the lens of industry.¹⁹

The British Dental Association, which represented FDI (the world dental trade association, of which the ADA is a member): The latest release from the FDI treaty representative reaffirms an earlier statement where they welcome amalgam phase down for environmental reasons.²⁰

On January 23, 2013, the International Dental Tribune covered the treaty story.²¹ According to the article,

The American Dental Association has announced that it is very satisfied with the results of the recent UN meeting on reducing and eliminating mercury release and exposure. The delegates agreed on binding requirements for countries to phase down dental amalgam, among other resolutions.

"We also recognize that we do have a responsibility to the environment," Daniel M. Meyer, DDS, senior vice president for science/professional affairs at the American Dental Association, told *Medscape Medical News.* "The House of Delegates passed a resolution to work with the [Environmental Protection Agency] to establish appropriate regulations."²²

In Nairobi on December 19, 2012, during the inception workshop²³ for the East Africa

²¹ The International Dental Tribune (accessible at

¹⁸ Australian Dental Industry Association (accessible at http://www.oralhealthgroup.com/news/un-convetion-confirms-phased-down-approach-for-dentalamaigam/1002002705/)
¹⁹ UNITO Project (conversible at the second second

¹⁹ UNEP-WHO Project (accessible at

http://www.fdiworldental.org/fdi-at-work/programme-for-atrica/unep-dental-amalgam-phase-do wnproject.aspx)

²⁰ British Dental Association, representing the FDI, the world dental trade association (accessible at <u>http://www.dentistry.co.uk/news/dentists-welcome-%E2%80%98phase-down%E2%80%99-mercury-treaty</u>)

http://www.dental-

tribune.com/articles/news/americas/11498_ada_welcomes_un_treaty_on_global_mercury_ph asedown.html)

²² American Dental Association re Environmental Protection Agency (accessible at http://www.medscape.com/viewarticle/778273

²³<u>http://www.unep.org/hazardoussubstances/Mercury/PrioritiesforAction/Products/Activities/EastAfricaDentalAmalgamPhase-DownProject/tabid/105844/Default.aspx</u>

WHO-UNEPAmalgam Phase Down project, which includes industry, **Case studies** demonstrating amalgam phase-down approach: Initial findings, a power point created by Mercury Policy Project/Tides Center was presented by UNEP staff.²⁴

In anticipation of this treaty, the issue of mercury toxicity, including from dental amalgam fillings, received national coverage in *The New York Times* in December 2012.²⁵ The UN mercury treaty follows in line with actions already taken by a number of countries. Indeed, Japan and Finland have implemented measures to greatly reduce the production and use of dental amalgams containing mercury,²⁶ and Norway, Sweden, and Denmark have virtually phased out its use via legal restrictions and prohibitions .²⁷ A 2012 report for the European Commission (EC) recommended phasing out amalgam in five years.²⁸

The subject matter has a clear nexus to the Company.

The Company is one of very few companies that drive production of dental amalgam. Its decisions regarding whether to produce, or phase out, dental amalgam will have an enormous impact on the flow of dental amalgam into the environment. In a UNEP list of manufacturers, Kerr is one of very few companies listed as manufacturing amalgam.²⁹³⁰ As a recent report explained: "The business of developing and marketing mercuryfree filling materials is high-tech, innovative, and spread among many more companies than the handful that market amalgam. Any move that further encourages mercury-free materials will also encourage investment, R&D, marketing and related commercial activities – not to mention increased exports – well beyond any that might take place among the staid amalgam producers. The overall benefits in this case, including increased competition and a steadily decreasing price for the product, are difficult to calculate with any precision, but they are clearly significant.^{*31}

As demonstrated by the recent Staff decision in AT&T (February 7, 2013) and many other cases cited above, the fact that a company does not do business at the point at which

http://ec.europa.eu/environment/chemicals/mercury/pdf/Final_report_11.07.12.pdf).

²⁴ http://mercurypolicy.org/wp-

content/uploads/2013/01/case_studies_amalgam_phase_down_mpp_final.pdf

²⁵ "If Mercury Pollution Knows No Borders, Neither Can Its Solution," Kate Galbraith, New York Times, December 12, 2012 (http://www.nytimes.com/2012/12/13/business/energy-environment/ifmercury-pollution-knows-no-borders-neither-can-its-solution.html? r=0)

²⁶ United Nations Environmental Programme & Arctic Monitoring and Assessment Programme Report, "Technical Background Report to the Global Atmospheric Mercury Assessment," page 10. (accessible at

http://www.chem.unep.ch/mercury/Atmospheric_Emissions/Technical_background_report.pdf). ²⁷ Reuters, "Dental Mercury Use Banned in Norway, Sweden and Denmark because Composites are

Adequate . . .," January 3, 2008 (http://www.reuters.com/article/2008/01/03/idUS108558+03-Jan-2008+PRN20080103).

²⁸ European Commission, Study on the potential for reducing mercury pollution from dental amalgam and batteries," July 11, 2012 (accessible at

²⁹http://www.unep.org/hazardoussubstances/Mercury/PrioritiesforAction/Products/Reports/tabid/4513/lang uage/en-US/Default.aspx.

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

http://www.toxicteeth.org/CMSTemplates/ToxicTeeth/pdf/The-Real-Cost-of-Dental-Mercury-final.aspx

materials are released to the environment does not prevent a nexus from applying. In the AT&T example, the proposal ask the Company to report on its methods of ensuring that batteries used in its data centers are not polluting the environment at the point of production or disposal. The Company had argued that what happened at those upstream and downstream locations in the supply chain did not have a nexus to the Company. The Proponent argued that the Company was well situated to address the issue of the environmental impacts of its activities, because of the volume of its usage of the batteries. The Staff found that the Proposal was not excludable under the ordinary business exclusion.

Similarly, in the present instance, the Company is very well situated to drive markets towards less mercury bearing dental amalgam. If it were to declare that it intends to phase down the use of mercury in dental amalgam, it would help to drive the market toward the less polluting options for fillings.

CONCLUSION

As demonstrated above, the Proposal is not excludable under Rule 14a-8(i)(5) or the Rule 14a-8(i)(7). Therefore, we request the Staff to inform the Company that the SEC proxy rules require denial of the Company's no-action request. In the event that the Staff should decide to concur with the Company, we respectfully request an opportunity to confer with the Staff.

Please call Sanford Lewis at (413) 549-7333 with respect to any questions in connection with this matter, or if the Staff wishes any further information.

Sanford Lewis

Attorney at Law

cc: Ronald O. Mueller, Gibson Dunn James F. O'Reilly, Danaher Corporation Valerie Heinonen, Dominican Sisters of Hope Catherine M. Rowan, Trinity Health Kathleen Coll, Catholic Health East Dianne Heinrich, Providence Trust Kathleen White, Benedictine Sisters of Baltimore

Page 13

APPENDIX A

PROPOSAL

Whereas:

Dental amalgam is composed of approximately 50% mercury, a reproductive and neurological toxicant. Mercury is a concern when it enters the environment through uncontrolled releases via dental office wastes, fecal matter, breathing, burial, and cremation.¹ Mercury can be transformed into methylmercury, which bioaccumulates and can adversely affect the nervous system of those who consume fish.²

At the 25th session of the Governing Council of the UN Environment Programme in 2009, more than 120 nations agreed to work toward legally binding measures to control mercury pollution and created an Intergovernmental Negotiating Committee (INC). Since then four INCs have been held in: Sweden, Japan, Kenya and Uruguay.³

In 2011, the World Health Organization released an expert group report⁴, which stated that amalgam poses a serious environmental health problem because it releases a "significant amount of mercury" into the environment, including atmosphere, surface water, groundwater, and soil. It affirmed: "When released from dental amalgam use into the environment through these pathways, mercury is transported globally and deposited. Mercury releases may then enter the human food chain especially via fish consumption."

The WHO report recommends "a switch in use of dental materials"⁵ away from amalgam, explaining "for many reasons restorative materials alternative to dental amalgam are desirable" and commits itself, urging all health agencies to join them, to "work for reduction of mercury and the development of a healthy environment." To accomplish this goal, "WHO will facilitate the work for a switch in use of dental materials."

DANAHER reports quantities of mercury contained in products sold in the U.S. Product manufacturers submit such information in compliance with 8 state laws in effect since January 2001. Statistics appear to indicate that DANAHER reported a 57% decline in total quantity of mercury used for dental amalgams between 2007 and 2010.

RESOLVED: Shareholders request that the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, by October 31, 2013 summarizing DANAHER's policies and plans for eliminating releases into the environment of mercury from DANAHER products.

Supporting Statement

Shareholders believe such report should include DANAHER's: (i) goals for reduction in its production of dental amalgam and associated reductions in mercury use; (ii) annual production and sales on usage of mercury in amalgam globally for the prior year; (iii) projected reduction in usage of mercury for each of the next four years; (iv) by what date, if any, DANAHER projects it will cease production of amalgam and (v) what DANAHER is doing to reduce costs of alternatives to dental amalgams.

¹ http://mpp.cclearn.org/wp-content/uploads/2008/08/benders-testimony.pdf

² www.epa.gov/ost/criteria/methylmercury/factsheet.html

³ http://www.unep.org/hazardoussubstances/Mercury/Negotiations/tabid/3320/Default.aspx

⁴ http://www.who.int/oral health/publications/dental material 2011.pdf

⁵ http://newmoa.org/prevention/mercury/imerc/notification/browsecompany.cfm?pid=92

Gibson, Dunn & Crutcher LLP

1050 Connecticut Avenue, N.W. Washington, DC 20036-5306 Tel 202.955.8500 www.gibsondunn.com

Ronald O. Mueller Direct: 202.955.8671 Fax: 202.530.9569 RMueller@gibsondunn.com

Client: 22614-00004

January 14, 2013

VIA EMAIL

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

Dear Ladies and Gentlemen:

This letter is to inform you that our client, Danaher Corporation (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 statement in support thereof received from Trinity Health, the Benedictine Sisters of Baltimore, the Dominican Sisters of Hope, Providence Trust and Catholic Health East (collectively, the "Proponents").

Pursuant to Rule 14a-8(j), we have:

- filed this letter with the Securities and Exchange Commission (the "Commission") no later than eighty (80) calendar days before the Company intends to file its definitive 2013 Proxy Materials with the Commission; and
- concurrently sent copies of this correspondence to the Proponents.

Rule 14a-8(k) and Staff Legal Bulletin No. 14D (Nov. 7, 2008) ("SLB 14D") provide that shareholder proponents are required to send companies a copy of any correspondence that the proponents elect to submit to the Commission or the staff of the Division of Corporation Finance (the "Staff"). Accordingly, we are taking this opportunity to inform the Proponents that if the Proponents elect to submit additional correspondence to the Commission or the Staff with respect to this Proposal, a copy of that correspondence should be furnished concurrently to the undersigned on behalf of the Company pursuant to Rule 14a-8(k) and SLB 14D.

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 2

THE PROPOSAL

The Proposal requests that "the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, by October 31, 2013 summarizing DANAHER's policies and plans for eliminating releases into the environment of mercury from DANAHER products." The supporting statement to the Proposal includes a statement asserting that the Company should include in the report "DANAHER's: (i) goals for reduction in its production of dental amalgam and associated reductions in mercury use; (ii) annual production and sales on usage of mercury in amalgam globally for the prior year; (iii) projected reduction in usage of mercury for each of the next four years; (iv) by what date, if any DANAHER projects it will cease production of amalgam and (v) what DANAHER is doing to reduce costs of alternatives to dental amalgams." A copy of the Proposal, as well as related correspondence from the Proponents, is attached to this letter as <u>Exhibit A</u>.

BASES FOR EXCLUSION

We believe that the Proposal may properly be excluded from the 2013 Proxy Materials pursuant to:

- Rule 14a-8(i)(5) because the Proposal relates to operations which account for less than five percent of the Company's total assets at the end of its most recent fiscal year, and for less than five percent of its net earnings and gross sales for its most recent fiscal year, and is not otherwise significantly related to the Company's business; and
- Rule 14a-8(i)(7) because the Proposal deals with a matter relating to the Company's ordinary business operations.

BACKGROUND

Dental amalgam, which is commonly used by dentists as a restorative material to fill cavities in teeth, is a mixture of metals composed of liquid mercury and a powder typically containing silver, tin and copper.¹ A recent U.S. Food and Drug Administration ("FDA")

¹ FDA, About Dental Amalgam Fillings, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/Den [Footnote continued on next page]

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 3

final rule issuance notes that the number of individuals with dental amalgam restorations is extremely high (tens of millions annually in the United States).²

While the use of amalgam is rapidly declining due to the decreased incidence of tooth decay and the development of dental amalgam substitutes, dentists still prefer to use amalgam in a variety of circumstances due to its strength and other properties. In addition, it is normally the least expensive filling material,³ helping ensure that dental care is available to those who cannot afford more expensive, cosmetically appealing materials such as composites and porcelain overlays.⁴ As stated by the U.S. Environmental Protection Agency ("EPA") in a fact sheet on common products containing mercury: "Amalgam is one of the most commonly used tooth fillings, and is considered to be a safe, sound, and effective treatment for tooth decay."⁵

In recent years, the two principal U.S. federal regulatory agencies that regulate dental amalgams (the FDA and the EPA) each have issued updated guidance regarding dental amalgam. In 2009, the FDA, which regulates amalgam as medical devices, ruled that on the basis of "valid scientific evidence," dental amalgam fillings are effective and safe for adults and children six or older, and also concluded that with respect to potentially sensitive

- ² Dental Devices: Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy, 74 Fed. Reg. 38686 (Aug. 4, 2009) [hereinafter 2009 FDA Rule].
- ³ See FDA, supra note 1 ("Dental amalgam fillings are strong and long-lasting, so they are less likely to break than some other types of fillings. Dental amalgam is the least expensive type of filling material.").
- ⁴ See AMER. DENTAL ASSOC., Dental Materials Chart, http://www.ada.org/sections/publicResources/pdfs/materials.pdf (last visited Dec.31, 2012), a copy of which is attached as <u>Exhibit C</u>.
- ⁵ EPA, *Mercury in Dental Amalgam*, http://www.epa.gov/mercury/dentalamalgam.html (last visited Jan. 10, 2013), a copy of which is attached as <u>Exhibit D</u>.

[[]Footnote continued from previous page]

talAmalgam/ucm171094.htm (last visited Dec. 31, 2012), a copy of which is attached as Exhibit B.

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 4

populations such as children younger than six years of age, the FDA would not expect to see any adverse health effects in these subpopulations. Specifically, the FDA concluded:

In determining the appropriate classification of dental amalgam, FDA has relied on valid scientific evidence, including \ldots several comprehensive reviews of the scientific literature and safety assessments, air monitoring standards for mercury vapor, biological monitoring standards for urine mercury and clinical studies. Based on its review of this information, FDA concludes that exposures to mercury vapor from dental amalgam are not associated with adverse health effects in the population age six and older. With respect to potentially sensitive populations, *i.e.*, fetuses, breastfed infants, and children under six years of age, FDA would not expect to see any adverse health effects in these subpopulations from mercury vapors released from dental amalgam, although clinical data are limited.⁶

Similarly, as the Centers for Disease Control and Prevention (CDC) also noted, "there is little scientific evidence that the health of the vast majority of people with dental amalgam is compromised, nor that removing amalgam fillings has any beneficial effect on health."⁷ Thus, the conclusions of the FDA and the CDC with respect to dental amalgam stand in sharp contrast to the rhetoric in the Proponent's supporting statement.

Furthermore, the recent actions of the EPA, which regulates the disposal of dental amalgam,⁸ are largely unrelated to the Company's business. Under the Clean Water Act, the EPA establishes national regulations in situations where it considers it necessary to reduce discharges of particular pollutants to surface waters and publicly owned treatment works. In September 2010, the EPA announced that it intends to propose a rule regarding the use by dental offices of amalgam separators when disposing of old fillings (although the EPA's

⁶ 2009 FDA Rule, *supra* note 2, at 38699.

⁷ EPA, supra note 5.

⁸ FDA, *About Dental Amalgam Fillings; Related Resources*, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171115.htm (last visited Dec. 31, 2012).

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 5

website does not indicate any subsequent activity with respect to this rule proposal).⁹ Additionally, in March 2011, the EPA enacted rules governing incineration at wastewater treatment plants, which rules are designed to keep several air pollutants, including mercury, from impacting the environment.¹⁰ The Company is not subject to the EPA's regulations because it does not operate dental offices or sewage treatment plants. However, the Company as part of its customer relations activities supports the EPA's initiatives to promote proper disposal of dental amalgam by dental offices. For example, the labels for the Company's amalgam products contain specific language regarding proper disposal and recycling.

ANALYSIS

The Proposal requests the issuance of a report on the Company's "policies and plans for eliminating releases into the environment of mercury" from the Company's products encompassing five specific topics: "(i) goals for reduction in [DANAHER's] production of dental amalgam and associated reductions in mercury use; (ii) annual production and sales on usage of mercury in amalgam globally for the prior year; (iii) projected reduction in usage of mercury for each of the next four years; (iv) by what date, if any, DANAHER projects it will cease production of amalgam and (v) what DANAHER is doing to reduce costs of alternatives to dental amalgams." When evaluating a proposal requesting the dissemination of a report, the Staff evaluates the substance of the matter to be addressed in the report. *See* Exchange Act Release No. 20091 (Aug. 16, 1983); *Johnson Controls, Inc.* (avail. Oct. 26, 1999).

⁹ EPA, EPA Will Propose Rule to Protect Waterways by Reducing Mercury from Dental Offices / Existing Technology is Available to Capture Dental Mercury, http://yosemite.epa.gov/opa/admpress.nsf/e77fdd4f5afd88a3852576b3005a604f/a640db2 ebad201cd852577ab00634848%21OpenDocument (Sept. 27, 2010).

Standard of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Sewage Sludge Incineration Units, 76 Fed. Reg. 15372 (EPA Mar. 21, 2011). These rules were subsequently amended in December 2012. See Regulatory Actions, http://www.epa.gov/airquality/combustion/actions.html.

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 6

I. The Proposal May Be Excluded Under Rule 14a-8(i)(5) Because It Relates To Operations Which Account For Less Than Five Percent Of The Company's Total Assets At The End Of Its Most Recent Fiscal Year, And For Less Than Five Percent Of Its Net Earnings And Gross Sales For Its Most Recent Fiscal Year, And Is Not Otherwise Significantly Related To The Company's Business.

Rule 14a-8(i)(5) permits the exclusion of a shareholder proposal relating to operations which account for less than five percent of a company's (i) total assets at the end of its most recent fiscal year, (ii) net earnings for the most recent fiscal year, and (iii) gross sales for the most recent fiscal year, and that is not otherwise significantly related to the company's business.

The Company has confirmed to us that its dental amalgam operations accounted for less than one-half of one percent of the Company's total assets as of the end of fiscal year 2012 and that such operations accounted for less than one-half of one percent of the Company's gross sales and net earnings for fiscal year 2012.¹¹ Furthermore, the Company does not expect these percentages to increase in the future. The quantitative importance of the Company's dental amalgam sales is clearly well beneath the thresholds specified in Rule 14a-8(i)(5).

Notwithstanding the very slight proportion of the Company's business that dental amalgam accounts for, the Staff has taken the position that "certain proposals, while relating to only a small portion of the issuer's operations, raise policy issues of significance to the issuer's business." Exchange Act Release No. 19135 (Oct. 14, 1982). This can occur where a particular corporate policy "may have a significant impact on other segments of the issuer's business or subject the issuer to significant contingent liabilities." *Id.* But even where a proposal raises a policy issue, the policy must be more than ethically or socially "significant in the abstract." It must have a "meaningful relationship to the business" of the company in question. *Lovenheim v. Iroquois Brands, Ltd.*, 618 F. Supp. 554, 561 and n. 16 (D.D.C. 1985); *see also Hewlett-Packard Co.* (avail. Jan. 7, 2003) (concurring in the exclusion of a proposal under Rule 14a-8(i)(5) where the proposal sought to require the company to relocate or close its offices in Israel and to send a letter regarding Israel's alleged violation of numerous United Nations Resolutions and human rights violations, because the matters implicated by the proposal were not significantly related to the company's operations in Israel); *J.P. Morgan & Co., Inc.* (avail. Feb. 5, 1999) (concurring in the exclusion of a

¹¹ Even if, as a result of the Proposal's reference to "reduc[ing] costs of alternatives to dental amalgams," the Proposal is interpreted more broadly as relating to dental amalgam and its alternatives, such as glass ionomers and composites, the thresholds in Rule 14a-8(i)(5) still would not be surpassed.

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 7

proposal under Rule 14a-8(i)(5) where the proposal mandated that the company discontinue banking services with Swiss entities until all claims by victims of the Holocaust and their heirs are settled and total restitution is made, because the amount of revenue, earnings, and assets attributable to J.P. Morgan's operations in Switzerland was less than five percent and the proposal was not otherwise significantly related to J.P. Morgan's business).

In this case, (1) there is not a significant relationship between the Company's sales of dental amalgam and the environmental releases that are the subject of the Proposal, and (2) in any event, the subject of the Proposal does not raise a significant policy issue.

No significant relationship to Company's business

The Proposal does not bear a significant relationship to the Company's operations. The topic of the report requested by the Proposal and the principal thrust and focus of the Proposal's supporting statement addresses "eliminating releases into the environment of mercury from DANAHER products." The Proponents devote a considerable amount of attention in the supporting statement to the alleged negative environmental effects of improper disposal of dental amalgam. As discussed in the supporting statement, the Proposal addresses the disposal of mercury by dental offices and alleged releases of mercury through other means such as burial or cremation of bodies that have amalgam fillings (which in many cases involve old fillings that have nothing to do with the Company's products). The Company, however, does not operate dental offices and does not engage in those businesses that, as addressed in the Proposal, are environmental pathways by which mercury from amalgam may enter the environment. The significance of this distinction is supported by the fact that the EPA's regulatory activity on the issue of mercury releases into the environment from dental amalgam focuses not on companies that sell dental amalgam, such as the Company, but instead on the operation of dental offices and sewage treatment facilities.¹²

In this respect, the Proposal is much like the one considered in *Arch Coal, Inc.* (avail. Jan. 19, 2007). There, the proposal requested that the company prepare a report on how it is responding to rising regulatory, competitive, and public pressure to significantly reduce carbon dioxide and other emissions from its current and proposed power plant operations. Although the company mined, processed, and marketed low-sulfur coal, the company did not have any current or proposed power plant operations and thus was not involved in the aspect of the environmental issue that the proposal addressed. Accordingly, the Staff concurred that the company could omit the proposal under Rule 14a-8(i)(5), noting that the company did

12 See EPA, supra note 5.

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 8

"not have any power plant operations." Here, the Proposal likewise is focused on enhancing the remedial actions of dental offices, sewage treatment facilities, and others that are beyond the Company's control. Therefore, the Proposal does not raise policy issues of significance to the Company's operations or business.

Nor does the Company's dental amalgam business have a significant impact on other portions of the Company's business or subject the Company to significant contingent liabilities. Although a few amalgam-related lawsuits were filed against the Company in the past, none have been filed since 2003, and all such suits, except for one, were won on summary judgment motions or were voluntarily dismissed by the plaintiffs. The one remaining suit was settled for an insignificant amount. If routine regulation and review by government agencies, and mere allegations against a common product that has been used for over 150 years, were sufficient to create a significant policy issue, the Rule 14a-8(i)(5) standard would have no substance. Instead, the Staff has on many occasions concurred that assertions such as those made by the Proponent are not sufficient to raise policy issues of significance to the Company's business. See Coca Cola Co. (avail. Jan. 22, 2007) (concurring in the exclusion of a proposal to stop "caffeinating" certain products and to label caffeinated products notwithstanding allegations that "caffeine is dangerous to the health of at least 3 million Americans" and that "[p]hysicians state that caffeine is addictive"); H.J. Heinz Co. (avail. June 2, 1999) (concurring in the exclusion of a proposal to cease using a certain food coloring as ordinary business notwithstanding an assertion that a report by the American Academy of Pediatrics indicated that the food coloring was suspected of causing an adverse reaction in children).

No significant policy issue

As with the products addressed in the foregoing no-action letters, the sale of dental amalgam has not risen to the status of a significant policy issue. We recognize that in other contexts the Staff has concurred that proposals addressing industrial discharge of mercury and other pollutants in the course of a company's operations may raise sufficiently significant policy issues in the context of other companies' business. It does not follow however that any and all discharges of mercury, under very different circumstances, raise the same policy issues, and under Rule 14a-8(i)(5) moreover, merely raising a policy issue in the abstract does not prevent a proposal from being excluded when the proposal is not significantly related to the company's business operations. For example, while the FDA has banned or restricted the

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 9

use of mercury in certain products,¹³ it has concluded that a ban of, or restriction on, the use of dental amalgam is not necessary or appropriate.¹⁴ Similarly, whereas the EPA has adopted numerous regulations on the discharge of mercury,¹⁵ the regulations it has actually adopted or announced an intent to propose with respect to mercury in dental amalgam focus on businesses in which the Company does not engage.¹⁶ The Proponents' supporting statement relies on selective quotations from reports produced by various organizations regarding purported risks from the sale or use of dental amalgam in an attempt to support its concerns regarding whether there are risks associated with dental amalgam. Yet the FDA, which, unlike the international organizations cited by the Proponents, has the power to create and enforce regulations governing the Company, came to the following important conclusions:

Based on these findings and the clinical data, FDA has concluded that exposures to mercury vapor from dental amalgam do not put individuals age six and older at risk for mercury-associated adverse health effects.... The exposures to children would therefore [also] be lower than the protective levels of exposure identified by ATSDR and EPA.... FDA has concluded that the existing data support a finding that infants are not at risk for adverse

14 See 2009 FDA Rule, supra note 2.

16 See EPA, supra note 9.

¹³ See, e.g., FDA, Ingredients Prohibited & Restricted by FDA Regulations, http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients /ucm127406.htm (last visited Dec. 31, 2012) ("The use of mercury compounds as cosmetic ingredients is limited to eye area cosmetics at concentrations not exceeding 65 parts per million . . . All other cosmetics containing mercury are adulterated and subject to regulatory action unless it occurs in a trace amount of less than 1 part per million").

¹⁵ The EPA regulates mercury levels relating to air, toxics, water and waste. *See* EPA, *Laws and Regulations*, http://www.epa.gov/mercury/regs.htm (last visited Dec. 31, 2012).

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 10

health effects from the breast milk of women exposed to mercury vapors from dental amalgam.¹⁷

Likewise here, for the reasons discussed above, there is no significant policy issue raised by the Proposal with respect to the Company's sale of dental amalgam, and any connection between the Company's business and the topics to be addressed in the report requested by the Proposal is even more attenuated. Stringing together assertions regarding alleged risks from dental amalgam to individuals and the environment cannot create a significant policy issue relating to the Company where a product has been in common use for over 150 years, is accepted for use by the FDA and is, in fact, widely used in the United States, and where the only EPA regulatory activity relates to businesses in which the Company is not engaged. As with *Hewlett-Packard* and *J.P. Morgan & Co.*, even if discharges of mercury may raise significant policy issues, and in any event the connection between the Company's business and the release of mercury into the environment is so attenuated that the Proposal is not significantly related to the Company's business. Therefore the Proposal is excludable in its entirety under Rule 14a-8(i)(5).

II. The Proposal May Be Excluded Under Rule 14a-8(i)(7) Because It Deals With A Matter Relating To The Company's Ordinary Business Operations.

Under well-established precedent, the Proposal is excludable under Rule 14a-8(i)(7) because it relates to the Company's ordinary business activities. According to the Commission release accompanying the 1998 amendments to Rule 14a-8, the term "ordinary business" refers to matters that are not necessarily "ordinary" in the common meaning of the word, but instead the term "is rooted in the corporate law concept of providing management with flexibility in directing certain core matters involving the company's business and operations." Exchange Act Release No. 40018 (May 21, 1998) (the "1998 Release"). The Commission noted in the 1998 Release that there are two central considerations on which this underlying policy rests: (1) "[c]ertain tasks are so fundamental to management's ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to direct shareholder oversight"; and (2) "the degree to which the proposal seeks to 'micro-

 FDA, Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy – Guidance for Industry and FDA Staff, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocument s/ucm073311.htm (July 28, 2009), a copy of which is attached as Exhibit E.

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 11

manage' the company by probing too deeply into matters of a complex nature upon which shareholders, as a group, would not be in a position to make an informed judgment."

Ordinary business operations

The Staff has previously recognized that proposals concerning product regulatory compliance and product research and development are excludable as relating to a company's ordinary business operations. For example, in *Applied Digital Solutions, Inc.* (avail. Apr. 25, 2006), the proposal requested that the company prepare a report on the harm that the continued sale and use of RFID chips, which the company used in a patient identification device that was regulated by the FDA, could have to the public's privacy, personal safety, and financial security. In addressing the ordinary business aspect of the proposal, the company noted:

The discretionary authority to develop products that comply with the FDA and other regulations should reside with the Company's management rather than its shareholders. Regulatory compliance issues, including product safety, have been found by the Staff to be within the ordinary business operations of a company. [Citations omitted.] In making those determinations, the Staff has implicitly recognized that the regulation of medical products and devices is a function assigned to the FDA

The Staff concurred in the proposal's exclusion, noting that the proposal related to the company's "ordinary business operations (i.e., product development)." See also PepsiCo, Inc. (avail. Feb. 28, 2012) (concurring in the exclusion of a proposal that the company not use the remains of aborted human beings in research and development because "[p]roposals concerning product research, development, and testing are generally excludable under rule 14a-8(i)(7)"); Pfizer Inc. (avail Jan. 23, 2006) (concurring in the exclusion under Rule 14a-8(i)(7) of a proposal requesting the company to provide a report on the effects of medications on certain persons as well as information on administering and monitoring the use of these medications as relating to "product research, development and testing"); E.I. Du Pont De Nemours and Co. (avail. Mar. 8, 1991) (concurring in the exclusion of a proposal relating to the phase-out of certain chemicals and research and development efforts to find substitutes, noting that the proposal related to "timing, research and marketing decisions").

As with *Applied Digital Solutions* and similar precedent, the Proposal relates to the Company's product regulatory compliance and product research and development and is therefore excludable. As noted above, the Proposal requests a detailed report delineating the Company's "policies and plans for eliminating releases into the environment of mercury from [the Company's] products" including, *inter alia*, "goals for reduction in its production

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 12

of dental amalgam," the date by which the Company will cease production of amalgam, and "what [the Company] is doing to reduce costs of alternatives to dental amalgams." The development and sale of medical devices, such as dental amalgam and its alternatives, require a deep understanding of the products, the needs and requirements of the medical professionals who will choose to use such products, and the regulatory framework applicable to such products. For example, the development of alternative medical products must be meticulously addressed with the Company's regulators, such as the FDA, and considerations relating to the applications for, and quality and affordability of, the product must be addressed with dentists and dental organizations who have the professional expertise that will be brought to bear in making the treatment decisions that implicate such products. These multivariable business decisions are not appropriate for direct shareholder oversight, as they involve inherently complex analyses and potential industry issues that are outside the expertise of shareholders. As such, requesting that the Company develop a wide-ranging report as to its future product development and business strategies for such medical products necessarily falls within the Company's ordinary business activities.

Moreover, as discussed above with respect to the Staff's position concurring with the exclusion of proposals in *Coca Cola Co.* (avail. Jan. 22, 2007) and *H.J. Heinz Co.* (avail. June 2, 1999), raising health or environmental concerns about products that are regulated does not prevent a proposal from being excluded under Rule 14a-8(i)(7). Similarly here, simply raising health concerns regarding actions by the Company's dental office customers and by dental patients does not alter the fact that the Proposal is addressing ordinary business issues that implicate the type of day-to-day operational oversight of a company's business that the ordinary business exclusion in Rule 14a-8(i)(7) was created to address. Such decisions fall within the Company's ordinary business operations, are fundamental to management's ability to control the Company's operations, and are not an appropriate matter for shareholder oversight.

No significant policy issue

As discussed above, we do not believe that the Proposal raises a significant policy issue. While the Staff has taken the position that in certain contexts company operations that generate mercury and pollute the environment may raise significant policy issues, the Staff also has concurred in other contexts that the sale of products containing mercury does not raise a significant policy issue. See The Home Depot, Inc. (avail. Mar. 4, 2009) (concurring with the exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on policy options to reduce consumer exposure and increase consumer awareness regarding mercury contained in the company's private label products).

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 13

Even if a portion of the report requested by the Proposal were viewed as implicating a significant policy issue with respect to the Company's amalgam products, the scope of the requested report is so broad that the preponderance of the report does address ordinary business matters. For example, the Proposal requests a report on "annual production and sales" of amalgam and what the Company "is doing to reduce costs of alternatives to dental amalgams." These topics do not pertain to the Proposal's environmental concerns, but instead directly involve the Company's ordinary business operations. As discussed above, it is not the production and sale of new dental amalgams that raise environmental concerns, but rather the incorrect disposal of amalgams. As such, the request for a report on the Company's production and sales of amalgam does not correlate to the Proposal's environmental concerns, but instead more broadly addresses the Company's ordinary business matters. Furthermore, the request for a report concerning what the Company "is doing to reduce costs of alternatives to dental amalgams" strays even further from the policy concerns of the Proposal. This topic moves well beyond the topic of the product safety of dental amalgams into the field of the Company's research and development and market analysis.

The Staff has previously held that proposals requesting reports on significant policy issues may nonetheless implicate ordinary business matters when the nature of the report requested in the proposal strays from the significant policy issue and implicates ordinary business issues. *See Ford Motor Co.* (avail Mar. 7, 2005); *General Motors Corp.* (avail. Mar. 30, 2005) (each concurring that a proposal requesting a report with a broad scope that included, but was not limited to, the environmental effects of carbon dioxide produced by the companies' products, could be excluded under Rule 14a-8(i)(7) due to the nature of the report requested under the proposals).

The Staff also consistently has concurred that a proposal may be excluded in its entirety when it calls for a report addressing both ordinary and non-ordinary business matters. For example, in *Union Pacific Corp.* (avail. Feb. 25, 2008), the Staff concurred with the exclusion of a proposal under Rule 14a-8(i)(7) recommending that the board of directors make available in the company's proxy statement information relevant to the company's efforts to safeguard the security of its operations arising from a terrorist attack, or other "homeland security" incident, as the proposal "include[d] matters relating to Union Pacific's ordinary business operations." *See also Wal-Mart Stores, Inc.* (avail. Mar. 15, 1999) (concurring in the exclusion of a proposal requesting a report to ensure that the company did not purchase goods from suppliers using unfair labor practices because the proposal also requested that the report address ordinary business matters). Here, because the requested report likewise clearly requires the Company to address ordinary business matters, the Proposal is excludable under Rule 14a-8(i)(7).

Office of Chief Counsel Division of Corporation Finance January 14, 2013 Page 14

CONCLUSION

Because of the nature of the report requested by the Proposal and the absence, or at best tenuous connection between the Company's amalgam products and the matters addressed by the Proposal and supporting statement, we believe that the entire Proposal may be excluded under Rule 14a-8(i)(5) and Rule 14a-8(i)(7). Based upon the foregoing analysis, we respectfully request that the Staff concur that it will take no action if the Company excludes the Proposal from its 2013 Proxy Materials.

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,

Rado. Mark

Ronald O. Mueller

Enclosures

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

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EXHIBIT A



Novi, Michigan

Catherine M. Rowan Director, Socially Responsible Investments 766 Brady Avenue, Apt. 635 Bronx, NY 10462 Phone: (718) 822-0820 Cell: (646) 305-6027 Fax: (718) 504-4787 E-Mail Address: rowan@bestweb.net

20555 Victor Parkway Livonia, MI 48152 ph 734-343-1000

www.trinity-health.org

November 20, 2012

James F. O'Reilly, Corporate Secretary Danaher Corporation 2200 Pennsylvania Avenue, N.W., Suite 800W Washington, D.C. 20037-1701

Dear Mr. O'Reilly:

Trinity Health, with an investment position of over \$2000 worth of shares of common stock in Danaher Corporation, looks for social and environmental as well as financial accountability in its investments.

Proof of ownership of common stock in Danaher Corporation is enclosed. Trinity Health has held stock in Danaher continuously for over one year and intends to retain the requisite number of shares through the date of the Annual Meeting.

Acting on behalf of Trinity Health, I am authorized to notify you of Trinity Health's intention to present the enclosed proposal for consideration and action by the stockholders at the next annual meeting, and I hereby submit it for inclusion in the proxy statement in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934.

Trinity Health is the primary filer for this proposal, represented by me. Please see my contact information in the heading of this letter.

We continue to be concerned about the impact of releasing mercury into the environment and submit the attached proposal with hopes that our Company will issue the requested report.

Sincerely,

Catherine Rowan

Catherine M. Rowan Director, Socially Responsibility Investments

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We serve together in Trinity Health, in the spirit of the Gospel, to heal body, mind and spirit to improve the health of our communities and to steward the resources entrusted to us.



Respect - Social Justice - Compassion - Care of the Poor and Underserved - Excellence

Whereas:

Dental amalgam is composed of approximately 50% mercury, a reproductive and neurological toxicant. Mercury is a concern when it enters the environment through uncontrolled releases via dental office wastes, fecal matter, breathing, burial, and cremation.¹ Mercury can be transformed into methylmercury, which bioaccumulates and can adversely affect the nervous system of those who consume fish.²

At the 25th session of the Governing Council of the UN Environment Programme in 2009, more than 120 nations agreed to work toward legally binding measures to control mercury pollution and created an Intergovernmental Negotiating Committee (INC). Since then four INCs have been held in: Sweden, Japan, Kenya and Uruguay.³

In 2011, the World Health Organization released an expert group report⁴, which stated that amalgam poses a serious environmental health problem because it releases a "significant amount of mercury" into the environment, including atmosphere, surface water, groundwater, and soil. It affirmed: "When released from dental amalgam use into the environment through these pathways, mercury is transported globally and deposited. Mercury releases may then enter the human food chain especially via fish consumption."

The WHO report recommends "a switch in use of dental materials"⁵ away from amalgam, explaining "for many reasons restorative materials alternative to dental amalgam are desirable" and commits itself, urging all health agencies to join them, to "work for reduction of mercury and the development of a healthy environment." To accomplish this goal, "WHO will facilitate the work for a switch in use of dental materials."

DANAHER reports quantities of mercury contained in products sold in the U.S. Product manufacturers submit such information in compliance with 8 state laws in effect since January 2001. Statistics appear to indicate that DANAHER reported a 57% decline in total quantity of mercury used for dental amalgams between 2007 and 2010.

RESOLVED: Shareholders request that the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, by October 31, 2013 summarizing DANAHER's policies and plans for eliminating releases into the environment of mercury from DANAHER products.

Supporting Statement

Shareholders believe such report should include DANAHER's: (i) goals for reduction in its production of dental amalgam and associated reductions in mercury use; (ii) annual production and sales on usage of mercury in amalgam globally for the prior year; (iii) projected reduction in usage of mercury for each of the next four years; (iv) by what date, if any, DANAHER projects it will cease production of amalgam and (v) what DANAHER is doing to reduce costs of alternatives to dental amalgams.

¹ http://mpp.cclearn.org/wp-content/uploads/2008/08/benders-testimony.pdf

² www.epa.gov/ost/criteria/methylmercury/factsheet.html

³ http://www.unep.org/hazardoussubstances/Mercury/Negotiations/tabid/3320/Default.aspx

⁴ http://www.who.int/oral_health/publications/dental_material_2011.pdf

⁵ http://newmoa.org/prevention/mercury/imerc/notification/browsecompany.cfm?pid=92

٠,



November 20, 2012

TO WHOM IT MAY CONCERN:

Please accept this letter as verification that as of November 20, 2012, Northern Trust as custodian held for the beneficial interest of Trinity Health 6,167 shares of Danaher Corporation stock.

As of November 20, 2012, Trinity Health has held at least \$2000 worth of Danaher Corporation stock continuously for over one year. Trinity Health has informed us it intends to continue to hold the required number of shares through the date of the company's annual meeting in 2013.

This letter is to confirm that the aforementioned shares of stock are registered with Northern Trust, Participant Number 2669, at the Depository Trust Company.

Sincerely

Wich *lasio* Nicholas Diasio

Account Manager - Trust Officer



20037\$1701 C052

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FAX

To:	James F. O'Reilly	Date: 12/3/12
	Corporate Secretary	
	Danaher Corporation	
FAX #:	202.828.0860	# of pages including cover:

From: Sr. Kathleen White, OSB

Benedictine Sisters of Baltimore Emmanuel Monastery 2229 W. Joppa Road Lutherville, MD 21093 Phone: 410-821-5792 FAX# 410-296-9560

Mr. O'Reilly,

The Benedictine Sisters of Baltimore are co-filing the stockholder resolution on a Report of the Use of Mercury Dental Amalgams by Danaher Corporation. Our letter and the stockholder resolution are attached. Thank you for your attention to this.

he Kachleen helite OSB

Sr. Kathleen White, OSB President Benedictine Sisters of Baltimore



December 3, 2012

James F. O'Reilly Corporate Secretary Danaher Corporation 2200 Pennsylvania Avenue, N.W., Suite 800W Washington, D.C. 20037-1701

Sent by Fax: 202.828.0860

Dear Mr. O'Reilly:

I am writing you on behalf of the Benedictine Sisters of Baltimore to co-file the stockholder resolution on a Report on the Use of Mercury Dental Amalgams. In brief, the proposal states: RESOLVED: Shareholders request that the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, by October 31, 2013 summarizing DANAHER's policies and plans for eliminating releases into the environment of mercury from DANAHER products.

I am hereby authorized to notify you of our intention to co-file this shareholder proposal with Trinity Health. I submit it for inclusion in the proxy statement for consideration and action by the shareholders at the 2013 annual meeting in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities and Exchange Act of 1934. A representative of the shareholders will attend the annual meeting to move the resolution as required by SEC rules.

We are the owners of 150 shares of Danaher Corp. stock and intend to hold \$2,000 worth through the date of the 2013 Annual Meeting. Verification of ownership will follow including proof from a DTC participant.

We truly hope that the company will be willing to dialogue with the filers about this proposal. Please note that the contact people for this resolution/proposal will be Cathy Rowan of Trinity Health at 718-822-0820 or at rowan@bestweb.net. Cathy Rowan as spokesperson for the primary filer is authorized to withdraw the resolution on our behalf.

Respectfully yours,

Je Karlleen takita, OSB

Sr. Kathleen White, OSB President

2229 West Joppa Road, Lutherville, MD 21093-4601 410-821-5792 • Fax 410-296-9560 bensrs@emmanuelosb.org • www.emmanuelosb.org

Whereas:

Dental amalgam is composed of approximately 50% mercury, a reproductive and neurological toxicant. Mercury is a concern when it enters the environment through uncontrolled releases via dental office wastes, fecal matter, breathing, burial, and cremation.¹ Mercury can be transformed into methylmercury, which bloaccumulates and can adversely affect the nervous system of those who consume fish.²

At the 25th session of the Governing Council of the UN Environment Programme in 2009, more than 120 nations agreed to work toward legally binding measures to control mercury pollution and created an Intergovernmental Negotiating Committee (INC). Since then four INCs have been held in: Sweden, Japan, Kenya and Uruguay.³

In 2011, the World Health Organization released an expert group report⁴, which stated that amalgam poses a serious environmental health problem because it releases a "significant amount of mercury" into the environment, including atmosphere, surface water, groundwater, and soil. It affirmed: "When released from dental amalgam use into the environment through these pathways, mercury is transported globally and deposited. Mercury releases may then enter the human food chain especially via fish consumption."

The WHO report recommends "a switch in use of dental materials"⁵ away from amalgam, explaining "for many reasons restorative materials alternative to dental amalgam are desirable" and commits itself, urging all health agencies to join them, to "work for reduction of mercury and the development of a healthy environment." To accomplish this goal, "WHO will facilitate the work for a switch in use of dental materials."

DANAHER reports quantities of mercury contained in products sold in the U.S. Product manufacturers submit such information in compliance with 8 state laws in effect since January 2001. Statistics appear to indicate that DANAHER reported a 57% decline in total quantity of mercury used for dental amalgams between 2007 and 2010.

RESOLVED: Shareholders request that the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, by October 31, 2013 summarizing DANAHER's policies and plans for eliminating releases into the environment of mercury from DANAHER products.

Supporting Statement

Shareholders believe such report should include DANAHER's: (i) goals for reduction in its production of dental amalgam and associated reductions in mercury use; (ii) annual production and sales on usage of mercury in amalgam globally for the prior year; (iii) projected reduction in usage of mercury for each of the next four years; (iv) by what date, if any, DANAHER projects it will cease production of amalgam and (v) what DANAHER is doing to reduce costs of alternatives to dental amalgams.

¹ http://mpp.cclearn.org/wp-content/uploads/2008/08/benders-testimony.pdf

² www.epa.gov/ost/criteria/methylmercury/factsheet.html

³ http://www.unep.org/hazardoussubstances/Mercury/Negotiations/tabid/3320/Default.aspx

http://www.who.int/oral_health/publications/dental_material_2011.pdf

LMIC

BMO (Global Asset Management

BMO Asset Management U.S. 11279 W Park Place, Suite 400 Milwaukee, WI 53224

Tet: \$20-497-5270 Fax: 414-212-0940

Joan.becks@bmo.com

December 3, 2012

James F. O'Reilly Corporate Secretary Danaher Corporation 2200 Pennsylvania Avenue, NW, Suite 800W Washington, DC 20037-1701

Via Fax Number 202-828-0860

Re: Co-filing of shareholder resolution - Use of Mercury Dental Alamgams

Dear Ms. Browdy:

As of December 3, 2012, The Benedictine Sisters of Baltimore held, and have continuously held for at least one year, 150 shares of Danaher Corporation Common Stock. These shares have been held with BMO Harris Bank, N.A./M&I Trust Company, DTC participant number 992.

If you need further information, please contact me.

Sincerely,

Joan Becks

Joan Becks Trust Officer

BMO (A part of BMO Financial Group

BMO Asset Management Corp.

Investment products are: NOT FDIC INSURED - MAY LOSE VALUE - NO BANK GUARANTEE.



Dominican Sisters of Hope

FINANCE OFFICE

November 21, 2012

James F. O'Reilly, Corporate Secretary Danaher Corporation 2200 Pennsylvania Avenue, N.W., Suite 800W Washington, D.C. 20037-1701

Dear Mr. O'Reilly:

On behalf of the Dominican Sisters of Hope, I am authorized to submit the following resolution which requests that the Board of Directors issue a report summarizing Danaher's policies and plans for eliminating releases into the environment of mercury from Danaher products. It is filed for inclusion in the 2013 proxy statement under Rule 14 a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934.

The Dominican Sisters of Hope understand that Danaher is using less mercury for dental amalgam fillings. We are glad to know that and suggest the alternatives be marketed more vigorously and less costly, thus protecting human health directly and indirectly by keeping this source for mercury pollution out of our environment.

The Dominican Sisters of Hope is the beneficial owner of at least \$2000 worth of shares of Danaher stock and verification of ownership from a DTC participating bank will follow. We have held the requisite number of shares for more than one year and will continue to hold the stock through the date of the annual shareowners' meeting in order to be present in person or by proxy. The Dominican Sisters is filing this resolution with Trinity Health, which is the primary filer and Catherine Rowan is the authorized contact person for the resolution. She may be reached at: rowan@bestweb.net or 718 822 0820.

Yours truly,

Daleine Neinone

Valerie Heinonen, o.s.u. Director, Shareholder Advocacy Mercy Investment Services, Inc. 205 Avenue C, NY NY 10009 heinonenv@juno.com

Whereas:

Dental amalgam is composed of approximately 50% mercury, a reproductive and neurological toxicant. Mercury is a concern when it enters the environment through uncontrolled releases via dental office wastes, fecal matter, breathing, burial, and cremation.¹ Mercury can be transformed into methylmercury, which bioaccumulates and can adversely affect the nervous system of those who consume fish.²

At the 25th session of the Governing Council of the UN Environment Programme in 2009, more than 120 nations agreed to work toward legally binding measures to control mercury pollution and created an Intergovernmental Negotiating Committee (INC). Since then four INCs have been held in: Sweden, Japan, Kenya and Uruguay.³

In 2011, the World Health Organization released an expert group report⁴, which stated that amalgam poses a serious environmental health problem because it releases a "significant amount of mercury" into the environment, including atmosphere, surface water, groundwater, and soil. It affirmed: "When released from dental amalgam use into the environment through these pathways, mercury is transported globally and deposited. Mercury releases may then enter the human food chain especially via fish consumption."

The WHO report recommends "a switch in use of dental materials"⁵ away from amalgam, explaining "for many reasons restorative materials alternative to dental amalgam are desirable" and commits itself, urging all health agencies to join them, to "work for reduction of mercury and the development of a healthy environment." To accomplish this goal, "WHO will facilitate the work for a switch in use of dental materials."

DANAHER reports quantities of mercury contained in products sold in the U.S. Product manufacturers submit such information in compliance with 8 state laws in effect since January 2001. Statistics appear to indicate that DANAHER reported a 57% decline in total quantity of mercury used for dental amalgams between 2007 and 2010.

RESOLVED: Shareholders request that the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, by October 31, 2013 summarizing DANAHER's policies and plans for eliminating releases into the environment of mercury from DANAHER products.

Supporting Statement

Shareholders believe such report should include DANAHER's: (i) goals for reduction in its production of dental amalgam and associated reductions in mercury use; (ii) annual production and sales on usage of mercury in amalgam globally for the prior year; (iii) projected reduction in usage of mercury for each of. the next four years; (iv) by what date, if any, DANAHER projects it will cease production of amalgam and (v) what DANAHER is doing to reduce costs of alternatives to dental amalgams.

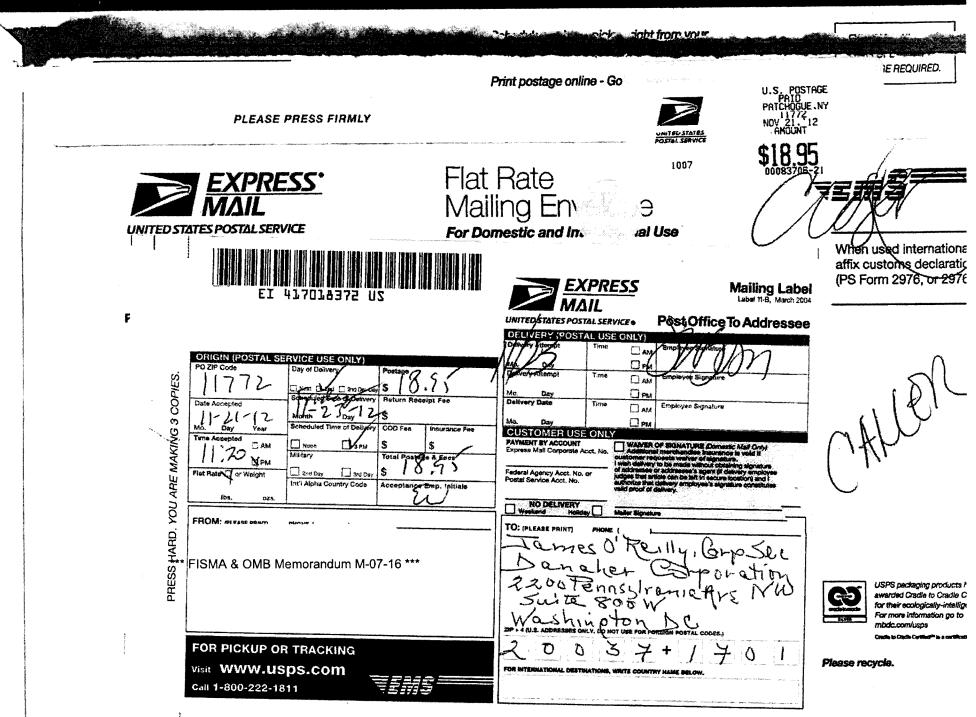
¹ http://mpp.cclearn.org/wp-content/uploads/2008/08/benders-testimony.pdf

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³ http://www.unep.org/hazardoussubstances/Mercury/Negotiations/tabid/3320/Default.aspx

⁴ http://www.who.int/oral_health/publications/dental_material_2011.pdf

⁵ http://newmoa.org/prevention/mercury/imerc/notification/browsecompany.cfm?pid=92



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To:

Providence Trust SAN ANTONIO, TEXAS Fax Transmittal 202-828-0860 James F. O'Reilly From: Sister Dianne Heinrich, CDP Phone Line (210) 667-3841 FAX Line (210) 431-9965 11/30/12 Date: Number of pages to follow: 2

Message:

Mr. O'Reilly, attached you will find a stockholder resolution from ProvidenceTrust.

Please contact me if you have any questions.

Vinter Dranne Heinich CAP

Sister Dianne Heinrich, CDP Trustee **Providence Trust** dheinrich@cdptexas.org

Treasurer's Office P.O. Box 37345 San Antonio, Texas 78237 Phone 210-587-1150 FAX 210-431-9965

PROVIDENCE TRUST

SAN ANTONIO, TEXAS

November 30, 2012

James F. O'Reilly Corporate Secretary Danaher Corporation 2200 Pennsylvania Avenue, N.W., Suite 800W Washington, D.C. 20037-1701

Sent by Fax: 202.828.0860

Dear Mr. O'Reilly:

I am writing you on behalf of Providence Trust to co-file the stockholder resolution on a Report on the Report on Use of Mercury Dental Amalgams. In brief, the proposal states: RESOLVED: Shareholders request that the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, by October 31, 2013 summarizing DANAHER's policies and plans for eliminating releases into the environment of mercury from DANAHER products.

I am hereby authorized to notify you of our intention to co-file this shareholder proposal with Trinity Health. I submit it for inclusion in the proxy statement for consideration and action by the shareholders at the 2013 annual meeting in accordance with Rule 14-a-8 of the General Rules and Regulations of the Securities and Exchange Act of 1934. A representative of the shareholders will attend the annual meeting to move the resolution as required by SEC rules.

We are the owners of \$2000 worth of Danaher Corp. stock and intend to hold \$2,000 worth through the date of the 2013 Annual Meeting. Verification of ownership will follow including proof from a DTC participant.

We truly hope that the company will be willing to dialogue with the filers about this proposal. Please note that the contact people for this resolution/proposal will be Cathy Rowan of Trinity Health at

718-822-0820 or at <u>rowan@bestweb.net</u>. Cathy Rowan as spokesperson for the primary filer is authorized to withdraw the resolution on our behalf.

Respectfully yours,

In Aranne Hernich CAP

Sr. Dianne Heinrich Trustee dheinrich@cdptexas.org

P.O. Box 37345 San Antonio, Texas 78237 Phone 210-434-1866 FAX 210-431-9965

Whereas:

Dental amalgam is composed of approximately 50% mercury, a reproductive and neurological toxicant. Mercury is a concern when it enters the environment through uncontrolled releases via dental office wastes, fecal matter, breathing, burial, and cremation.¹ Mercury can be transformed into methylmercury, which bioaccumulates and can adversely affect the nervous system of those who consume fish.²

At the 25th session of the Governing Council of the UN Environment Programme in 2009, more than 120 nations agreed to work toward legally binding measures to control mercury pollution and created an Intergovernmental Negotiating Committee (INC). Since then four INCs have been held in: Sweden, Japan, Kenya and Uruguay.³

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RESOLVED: Shareholders request that the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, by October 31, 2013 summarizing DANAHER's policies and plans for eliminating releases into the environment of mercury from DANAHER products.

Supporting Statement

Shareholders believe such report should include DANAHER's: (i) goals for reduction in its production of dental amaigam and associated reductions in mercury use; (ii) annual production and sales on usage of mercury in amalgam globally for the prior year; (iii) projected reduction in usage of mercury for each of the next four years; (iv) by what date, if any, DANAHER projects it will cease production of amalgam and (v) what DANAHER is doing to reduce costs of alternatives to dental amalgams.

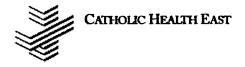
¹ http://mpp.cclearn.org/wp-content/uploads/2008/08/benders-testimony.pdf

² www.epa.gov/ost/criteria/methylmercury/factsheet.html

³ http://www.unep.org/hazardoussubstances/Mercury/Negotiations/tabid/3320/Default.aspx

http://www.who.int/oral_health/publications/dental_material_2011.pdf

³ http://newmoa.org/prevention/mercury/imerc/notification/browsecompany.cfm?pid=92



Treasury MS 222 3805 West Chester Pike, Ste. 100 Newtown Square, PA 19073-2329 kcoll@che.org 610-355-2035 fax 610-355-2050

November 26, 2012

James F. O'Reilly, Corporate Secretary Danaher Corporation 2200 Pennsylvania Avenue, N.W. Suite 800W Washington D .C. 20037-1701

RE: Shareholder Proposal for 2013 Annual Meeting

Dear Mr. O'Reilly:

Catholic Health East, one of the largest Catholic health care systems in the U.S. is a long-term, faithbased shareowner of Danaher Corporation. Catholic Health East seeks to reflect its Mission and Core Values while looking for social, environmental as well as financial accountability in its investments.

As a health care system, Catholic Health East continues to be concerned about the impact of releasing mercury into the environment. Therefore, Catholic Health East is co-filing the enclosed resolution, with the primary filer, Trinity Health represented by Catherine Rowan. We authorize Catherine Rowan to withdraw the resolution on our behalf when appropriate.

The enclosed resolution is for consideration and action by the shareholders at the next meeting. I hereby submit it for inclusion in the proxy statement in accordance with Rule 14 a-8 of the general rules and regulations of the Security and Exchange Act of 1934.

Catholic Health East is beneficial owner of at least \$2,000 worth of Danaher Corp. stock. We have held these shares continuously for more than one year and will continue to hold at least \$2,000 of stock until after the 2013 shareholder meeting. The verification of our ownership position will be provided by our custodian, BNY Mellon and will follow under separate cover.

Catholic Health East remains open for productive dialogue which could lead to a withdrawal of the resolution. Thank you for your attention to this matter.

Sincerely,

Lister Kaskeen Cole, 119.

Sister Kathleen Coll, SSJ Administrator, Shareholder Advocacy

cc: Catherine Rowan, Trinity Health The Interfaith Center on Corporate Responsibility

Whereas:

Dental amalgam is composed of approximately 50% mercury, a reproductive and neurological toxicant. Mercury is a concern when it enters the environment through uncontrolled releases via dental office wastes, fecal matter, breathing, burial, and cremation.¹ Mercury can be transformed into methylmercury, which bioaccumulates and can adversely affect the nervous system of those who consume fish.²

At the 25th session of the Governing Council of the UN Environment Programme in 2009, more than 120 nations agreed to work toward legally binding measures to control mercury pollution and created an Intergovernmental Negotiating Committee (INC). Since then four INCs have been held in: Sweden, Japan, Kenya and Uruguay.³

In 2011, the World Health Organization released an expert group report⁴, which stated that amalgam poses a serious environmental health problem because it releases a "significant amount of mercury" into the environment, including atmosphere, surface water, groundwater, and soil. It affirmed: "When released from dental amalgam use into the environment through these pathways, mercury is transported globally and deposited. Mercury releases may then enter the human food chain especially via fish consumption."

The WHO report recommends "a switch in use of dental materials"⁵ away from amalgam, explaining "for many reasons restorative materials alternative to dental amalgam are desirable" and commits itself, urging all health agencies to join them, to "work for reduction of mercury and the development of a healthy environment." To accomplish this goal, "WHO will facilitate the work for a switch in use of dental materials."

DANAHER reports quantities of mercury contained in products sold in the U.S. Product manufacturers submit such information in compliance with 8 state laws in effect since January 2001. Statistics appear to indicate that DANAHER reported a 57% decline in total quantity of mercury used for dental amalgams between 2007 and 2010.

RESOLVED: Shareholders request that the Board of Directors issue a report, produced at reasonable cost and excluding proprietary information, by October 31, 2013 summarizing DANAHER's policies and plans for eliminating releases into the environment of mercury from DANAHER products.

Supporting Statement

Shareholders believe such report should include DANAHER's: (i) goals for reduction in its production of dental amalgam and associated reductions in mercury use; (ii) annual production and sales on usage of mercury in amalgam globally for the prior year; (iii) projected reduction in usage of mercury for each of the next four years; (iv) by what date, if any, DANAHER projects it will cease production of amalgam and (v) what DANAHER is doing to reduce costs of alternatives to dental amalgams.

¹ http://mpp.cclearn.org/wp-content/uploads/2008/08/benders-testimony.pdf

² www.epa.gov/ost/criteria/methylmercury/factsheet.html

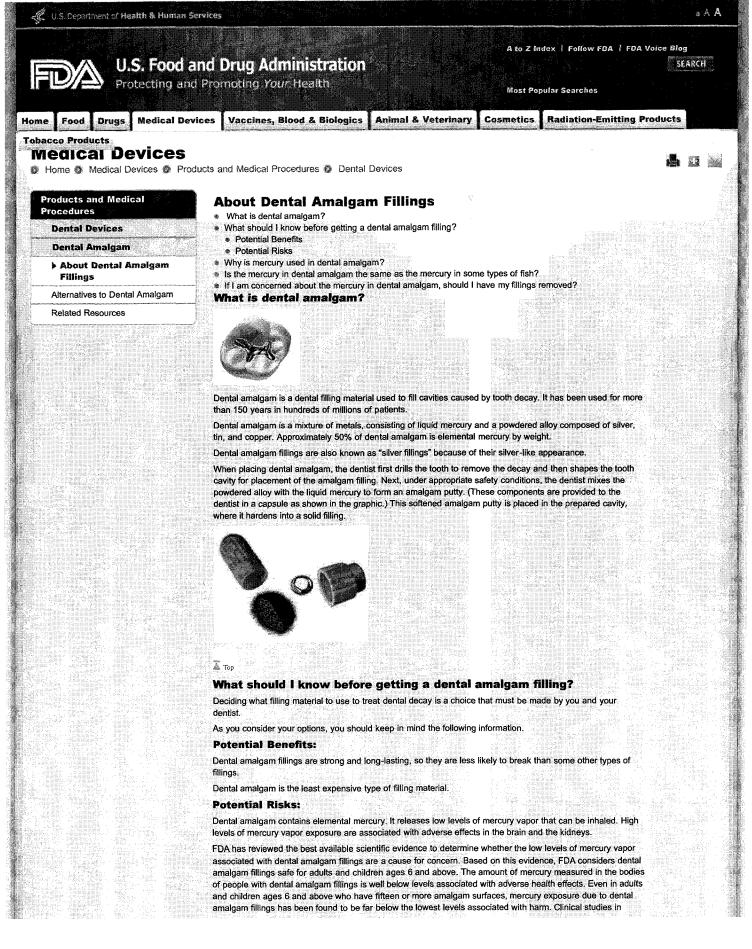
³ http://www.unep.org/hazardoussubstances/Mercury/Negotiations/tabid/3320/Default.aspx

⁴ http://www.who.int/oral_health/publications/dental_material_2011.pdf

⁵ http://newmoa.org/prevention/mercury/imerc/notification/browsecompany.cfm?pid=92

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EXHIBIT B



adults and children ages 6 and above have also found no link between dental amalgam fillings and health problems.

There is limited clinical information about the potential effects of dental amalgam fillings on pregnant women and their developing fetuses, and on children under the age of 6, including breastfed infants. However, the estimated amount of mercury in breast milk attributable to dental amalgam is low and falls well below general levels for oral intake that the Environmental Protection Agency (EPA) considers safe. FDA concludes that the existing data support a finding that infants are not at risk for adverse health effects from the breast milk of women exposed to mercury vapor from dental amalgam. The estimated daily dose of mercury vapor in children under age 6 with dental amalgams is also expected to be at or below levels that the EPA and the Centers for Disease Control and Prevention (CDC) consider safe. Pregnant or nursing mothers and parents with young children should talk with their dentists if they have concerns about dental amalgam.

Some individuals have an allergy or sensitivity to mercury or the other components of dental amalgam (such as silver, copper, or tin). Dental amalgam might cause these individuals to develop oral lesions or other contact reactions. If you are allergic to any of the metals in dental amalgam, you should not get amalgam fillings. You can discuss other treatment options with your dentist.

For more information on FDA's scientific review and findings, see the new "Information for Use" statement required in dental amalgam labeling, and other documents in the Related Resources section.

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Why is mercury used in dental amalgam?

Approximately half of a dental amalgam filling is liquid mercury and the other half is a powdered alloy of silver, tin, and copper. Mercury is used to bind the alloy particles together into a strong, durable, and solid filling. Mercury's unique properties (it is the only metal that is a liquid at room temperature and that bonds well with the powdered alloy) make it an important component of dental amalgam that contributes to its durability.

👗 Top

Is the mercury in dental amalgam the same as the mercury in some types of fish?

No. There are several different chemical forms of mercury: elemental mercury, inorganic mercury, and methylmercury. The form of mercury associated with dental amalgam is elemental mercury, which releases mercury vapor. The form of mercury found in fish is methylmercury, a type of organic mercury. Mercury vapor is mainly absorbed by the lungs. Methylmercury is mainly absorbed through the digestive tract. The body processes these forms of mercury differently and has different levels of tolerance for mercury vapor and methylmercury. Methylmercury is more toxic than mercury vapor.

👗 Top

If I am concerned about the mercury in dental amalgam, should I have my fillings removed?

If your fillings are in good condition and there is no decay beneath the filling, FDA does not recommend that you have your amalgam fillings removed or replaced. Removing sound amalgam fillings results in unnecessary loss of healthy tooth structure, and exposes you to additional mercury vapor released during the removal process.

However, if you believe you have an allergy or sensitivity to mercury or any of the other metals in dental amalgam (such as silver, tin, or copper), you should discuss treatment options with your dentist.

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Page Last Updated: 08/11/2009

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Accessibility Contact FDA	Careers FDA Basics FOIA	No Fear Act Site Map Transparency Website Policies
U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 Ph. 1-888-INFO-FDA (1-888-463-6332) Email FDA	Combination Products Advisory Committees Science & Research Regulatory Information Safety	U.S. Department of Health & Human Services
T <u>slov</u> 🖂 🖾 🖬 🔛 🛤 🛤	Emergency Preparedness International Programs	
For Government For Press	News & Events Training and Continuing Education	
· · · · ·	Inspections/Compliance State & Local Officials Consumers	

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EXHIBIT D





Science & Technology

En español

Site Map

Related Links

Mercurv

Search: All EPA This Area You are here: EPA Home » Mercury » Dental Amalgam

Mercury in Dental Amalgam

Quick Links

Share

- Best management practices for environmentally responsible dentistry
- Environmentally Responsible Dentistry Teaching Module
- Dental Amalgam Waste Collections and Recycling Campaign for Dentists

Information about Dental Amalgam from Other U.S. **Government Agencies**

- Food and Drug
- Administration (FDA) Centers for Disease Control and Prevention (CDC)

Using Dental Amalgam

- What is dental amalgam?
- Are dental amalgam fillings safe?
- Are there alternatives to using dental amalgam fillings?
- How much mercury is used in dental amalgam?

Mercury Pollution from Amalgam Waste

- How does amalgam waste affect the environment?
- How much mercury contamination in wastewater comes from dental sources?

What Dentists Can Do To Prevent Mercury Pollution

 How can dentists capture and recycle dental amalgam waste?

EPA, State, Tribal, and Community Actions

- What is EPA doing to reduce mercury pollution from dental waste?
- · What are states, tribes and communities doing to reduce mercury pollution from dental waste?

Using Dental Amalgam

What is Dental Amalgam?

Dental amalgam, sometimes referred to as "silver filling," is a silver-colored material used to fill (restore) teeth that have cavities. Dental amalgam is made of two nearly equal parts: liquid mercury and a powder containing silver, tin, copper, zinc and other metals. Amalgam is one of the most commonly used tooth fillings, and is considered to be a safe, sound, and effective treatment for tooth decay.

∲Top of page

Are Dental Amalgam Fillings Safe?

When amalgam fillings are placed in or removed from teeth, they can release a small amount of mercury vapor. Amalgam can also release small amounts of mercury vapor during chewing, and people can absorb these vapors by inhaling or ingesting them. High levels of mercury vapor exposure are associated with adverse effects in the brain and the kidneys.

Since the 1990s, several federal agencies have reviewed the scientific literature looking for links between dental amalgam and health problems. According to the Centers for Disease Control and Prevention (CDC), there is little scientific evidence that the health of the vast majority of people with dental amalgam is compromised, nor that removing amalgam fillings has any beneficial effect on health.

<u>A 2004 review of the scientific literature conducted for the U.S. Public Health Service EXIT Disclaimer</u> found "insufficient evidence of a link between dental mercury and health problems, except in rare instances of allergic reaction." <u>View a CDC factsheet that presents more information on dental</u> amalgam use, benefits and health issues.

FDA Classification of Dental Amalgam as a Medical Device

Dental amalgam is considered to be a <u>medical device, and is regulated by the Food</u> <u>and Drug Administration (FDA)</u>. FDA is responsible for ensuring that dental amalgam is reasonably safe and effective, and that, among other things, the product labeling seen by dentists has adequate directions for use and includes any appropriate warnings.

In 2008, FDA reviewed the best available scientific evidence to determine whether the low levels of mercury vapor associated with dental amalgam fillings are a cause for concern. Based on this evidence, FDA considers dental amalgam fillings safe for adults and children ages six and above. FDA recommends that patients in specific populations who might be more vulnerable to mercury (pregnant women and their fetuses, and children under the age of six, including those who are breastfed), speak with their dentists about any concerns they have about the potential effects of using dental amalgam.

Learn more about the potential benefits and risks of dental amalgam at US FDA's website.

∲Top of page

Are There Alternatives to Using Dental Amalgam Fillings?

Presently, there are five other types of restorative materials for tooth decay:

- resin composite,
- glass ionomer,
- resin ionomer,
- porcelain, and
- gold alloys.

The choice of dental treatment rests with dental professionals and their patients, so talk with your dentist about available dental treatment options. The American Dental Association provides a <u>brochure for dental patients (PDF)</u> (6 pp, 133K, <u>about PDF</u>) (EXIT Disclaimer) on the advantages and disadvantages of various types of dental fillings.

http://www.epa.gov/mercury/dentalamalgam.html[1/7/2013 6:23:48 PM]

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∲Top of page

How Much Mercury Is Used in Dental Amalgam?

The Interstate Mercury Education and Reduction Clearinghouse (IMERC), managed by the Northeast Waste Management Officials' Association, reports that the total mercury sold in dental amalgam in 2004 was 30.4 tons (26% of mercury in all products). This total is based on data submitted to IMERC by five dental amalgam manufacturers who represent the entire U.S. market for dental amalgam capsules. More detailed information can be found in the online <u>IMERC fact sheet</u>, *Mercury Use in Dental Amalgam*, and its 2008 report, *Trends in Mercury Use in Products* (*PDE*) (30 pp., 2.8 MB, <u>about PDF</u>)

The amount of mercury used in consumer products dropped 83% between 1980 and 1997, largely as a result of federal legislation and state regulatory limits on mercury usage in batteries and EPA's regulatory ban on mercury in paint.

Amalgam use in the U.S. is slowly declining because the incidence of dental decay is decreasing and because improved substitute materials are now available for certain applications. The decreasing cost of non-mercury substitutes has also contributed to a decline in consumer demand for amalgam.

Top of page

Mercury Pollution from Amalgam Waste

How Does Amalgam Waste Affect The Environment?

If improperly managed by dental offices, dental amalgam waste can be released into the environment. Dentists should use dental amalgam separators to catch and hold the excess amalgam waste coming from office spittoons. Without dental amalgam separators, the excess amalgam waste will be released to the sewers via drains in the dental offices. While <u>Publicly-Owned Treatment Works (POTWs)</u> have around a 90% efficiency rate of removing amalgam from wastewaters, a small amount of waste amalgam is discharged from POTWs into surface waters around the plants.

At the treatment plant, the amalgam waste settles out as a component of sewage sludge that is then disposed:

- in landfills,
- through incineration, or
- by applying the sludge to agricultural land as fertilizer.

Learn about EPA's March 21, 2011 sewage sludge incinerator rule that will help keep mercury from dental amalgam waste out of the environment.

If the amalgam waste is sent to a landfill, the mercury may be released into the groundwater or air. If the mercury is incinerated, mercury may be emitted to the air from the incinerator stacks. And finally, if mercury-contaminated sludge is used as an agricultural fertilizer, some of the mercury used as fertilizer may also evaporate to the atmosphere. Through precipitation, this airborne mercury eventually gets deposited onto water bodies, land and vegetation. Some dentists throw their excess amalgam into special medical waste ("red bag") containers, believing this to be an environmentally safe disposal practice. If waste amalgam solids are improperly disposed in medical red bags, however, the amalgam waste may be incinerated and mercury may be emitted to the air from the incinerator stacks. This airborne mercury is eventually deposited into water bodies and onto land.

Mercury amalgam also accumulates on dental supplies, such as cotton swabs and gauze, and these materials are usually deposited in the regular trash. In local areas where trash is incinerated, the mercury in this trash can be released via air emissions.

∲Top of page

How Much Mercury Contamination in Wastewater Comes From Dental Sources?

Mercury from dental offices contributes significantly to the overall mercury contamination in wastewater. In an <u>August 2008 report (PDF)</u> (76 pp., 1.0 MB, <u>about PDF</u>) on the dental industry, EPA estimated that in 2008 there were approximately 122,000 dental offices (approximately 160,000 dentists) that used or removed dental amalgam in the U.S., and that those offices discharged approximately 3.7 tons of mercury each year to POTWs. Dental offices were found in 2003 to have been the source of 50 percent of all mercury pollution entering POTWs.

A 2002 study by the New York Academy of Sciences, <u>Pollution Prevention and Management</u> <u>Strategies for Mercury in the New York/New Jersey Harbor (PDF)</u> (116 pp., 799K, <u>about PDF</u>) <u>EXIT Disclaimer</u>, indicated that as much as 40 percent of total mercury loadings in the New York/New Jersey harbor and watershed may have come from dental offices. In another study in 2002, <u>Mercury Source Control & Pollution Prevention Program Evaluation (PDF)</u> <u>EXIT Disclaimer</u> (62 pp., 240K, <u>about PDF</u>), the <u>National Association of Clean Water Agencies</u> (NACWA) estimated that nearly 40 percent of the mercury in the nation's wastewater system came from dental offices, and that mercury discharged from dental offices far exceeded all other commercial and residential sources, each of which was below ten percent.

∲Top of page

EPA, State, Tribal and Community Actions

What is EPA Doing to Reduce Mercury Pollution from Dental Waste?

Effluent Guideline Rulemaking

EPA regulates the discharge of pollutants to wastewater by establishing national regulations known as "effluent guidelines" and "pretreatment standards." These regulations reduce pollutant discharges from specific industries that discharge either directly to surface waters or indirectly through POTWs. <u>EPA announced in September 2010</u> the start of <u>regulatory development (called an effluent guideline rulemaking) to reduce discharges of mercury from dental offices.</u>

The new regulation will establish requirements for the discharge of dental amalgam and mercury, based on the application of the best technology capable of removing the amalgam. EPA intends to focus its technology assessment on amalgam separators.

∲Top of page

Sewage Sludge Incinerator Rule

Dental amalgam waste settles out as a component of sewage sludge at wastewater treatment plants. In February 2011, EPA issued a new rule that limits air emissions for mercury and eight other hazardous air pollutants from publicly owned incinerators that burn sewage sludge. <u>This rule</u>, <u>published in the Federal Register on March 21, 2011 (PDF)</u> (83pp., 579K, <u>about PDF</u>) <u>EXIT Disclaimer</u>, is a major step toward keeping mercury releases from dental amalgam waste out of the environment. Learn more about the rule at EPA's <u>Emission Standards for Boilers and Process</u> Heaters and Commercial/Industrial Soild Waste Incinerators site.

∲Top of page

Environmentally Responsible Dentistry Teaching Module

The Environmentally Responsible Dentist – Dental Amalgam Recycling: Principles, Pathways and Practice (NOTE: registration required to view document) - EPA and Marquette University's School of Dentistry developed a teaching module to educate dental students on proper amalgam waste

management. The module aims to raise dental students' awareness of the dental amalgam waste issue and to provide the students with practical steps to reduce the release of amalgam waste to the environment. The module highlights four actions to properly manage amalgam waste. These actions are abbreviated as <u>GRIT</u>: "Gray Bag It," "Recycle It," "Install It," and "Teach It." The GRIT steps highlight <u>ADA's best management practices for amalgam waste</u> [EXIT Disclaimer] and encourage dental students to practice environmentally responsible dentistry.

∲Top of page

Dental Amalgam Waste Collection and Recycling Campaign for Dentists

EPA is working with dental amalgam manufacturers to encourage proper dental amalgam waste management as a public education effort under section 8001 of the Solid Waste Disposal Act. The Agency has developed inserts to be included in dental amalgam packages, which will then be distributed to dentists. The insert encourages dentists to collect mercury amalgam waste using gray bags and amalgam separators, and to send the waste for recycling at a <u>RCRA-permitted</u> mercury retorter or recycler.

Dental amalgam waste is a significant contributor of mercury discharges to municipal wastewater treatment facilities, often referred to as "publicly-owned treatment works" (POTWs). While POTWs have a high efficiency rate of removing amalgam from wastewaters (around 90%), a small amount of waste amalgam is discharged from POTWs into surface waters around the plants. Approximately 50% of mercury entering POTWs comes from dental amalgam waste. Dental offices discharge approximately 3.7 tons of mercury each year to POTWs.

EPA highly encourages dental amalgam manufacturers to use an EPA-provided insert in their dental amalgam packaging. The insert can be pressed into the lid, placed in the packaging, or adhered as a sticker.



View and print Dental Amalgam Insert (Red) (PDF) View and print Dental Amalgam Insert (Yellow) (PDF)

Dental amalgam manufacturers should keep these conditions in mind if they choose to use these inserts in their dental amalgam products:

- EPA cannot and does not endorse any particular product or service.
- Companies cannot use the EPA seal, identifier or logo for their own promotional purposes.
- The insert templates cannot be altered in any way, such as adding a company logo.

∲Top of page

What are States, Tribes, and Communities Doing to Reduce Mercury Pollution from Dental Waste?

Many state and tribal environmental agencies require local wastewater treatment facilities to meet very low mercury effluent limits in response to three key factors:

- EPA's <u>water quality criterion for human health of 0.3 milligrams of methylmercury per</u> <u>kilogram of fish tissue</u>. The criterion is the maximum advisable concentration of methylmercury in freshwater and estuarine fish and shellfish tissue that is protective of consumers of fish and shellfish.
- The increasing number of <u>mercury-related fish consumption advisories</u> being issued across the country.

• The availability of more sensitive analytical techniques that allow wastewater treatment agencies and regulatory agencies to better measure discharges of mercury from POTWs.

Some state and local governments have implemented mandatory and voluntary programs to reduce dental mercury discharges. More information can be found in <u>EPA's Health Services Industry</u> <u>Detailed Study: Dental Amalgam (August 2008) (PDF)</u> (76 pp, 1.0 MB, <u>about PDF</u>). The <u>National</u> <u>Conference of State Legislatures lists state legislature internet links</u> <u>Exit Disclaimer</u>, including links to information on state laws requiring dentists to install amalgam separators.

Increasing numbers of local POTW pretreatment programs are beginning to require dental offices to reduce their discharges of mercury. The NACWA has published information for local wastewater treatment agencies on the issue of mercury contamination of wastewater. In 2006, NACWA published a paper titled <u>Controlling Mercury in Wastewater Discharges from Dental Clinics</u> (<u>PDF</u>) (January 2006) (14 pp, 232K, <u>about PDF</u>) **EXIT Disclaimer** to help POTWs and other organizations understand some of the technical issues associated with the generation of dental clinic wastewater, and to provides introductory information for those communities considering formal programs requiring the installation of amalgam separators.

The Quicksilver Caucus (QSC), a coalition of state government associations, has published its <u>"Dental Mercury Amalgam Waste Management White Paper" (PDF)</u> (April 2008) (24 pp, 100K, <u>about PDF</u> <u>EXIT Disclaimer</u>) to help states determine how to reduce sources of dental mercury amalgam released to the environment from the dental sector. The paper provides information on successful state and local amalgam separator requirements, amalgam alternatives, and innovative approaches to reducing mercury amalgam releases. The QSC has also published <u>Case Studies of</u> <u>Five Dental Mercury Amalgam Separator Programs (PDF)</u> (May 2008) (20 pp, 87K, <u>about PDF</u>).

∲Top of page

What Dentists Can Do to Prevent Mercury Pollution

How Can Dentists Capture and Recycle Dental Amalgam Waste?

State Requirements

Some states have mandatory dental amalgam program requirements, including installation of amalgam separators. Specifics on state requirements can be found at EPA's August 2008 <u>Health</u> <u>Services Industry Detailed Study: Dental Amalgam (PDF)</u> (76 pp, 1 MB, <u>about PDF</u>) <u>EXIT Disclaimer</u>. Additionally, the <u>National Conference of State Legislatures lists state legislature internet links,</u> including links to information on state laws requiring dentists to install amalgam separators

∲Top of page

Best Management Practices

Most dental offices currently use some type of basic filtration system to reduce the amount of mercury solids passing into the sewer system. The installation of amalgam separators, which generally have a removal efficiency of 95%, can further reduce discharges to wastewater. In October 2007, the American Dental Association (ADA) adopted its new <u>Best Management Practices</u> for Amalgam Waste (PDF) (8 pp, 118K, about PDE) [EXIT Disclaimer), which recommends two very important and effective "best practices":

- the use of dental amalgam separators, and
- the recycling or retorting of captured amalgam solid waste.

∲Top of page

G.R.I.T.

The G.R.I.T. actions below highlight the American Dental Association's (ADA's) best management

<u>practices</u> for amalgam waste. EPA encourages both dentists and dental students to employ the GRIT actions in their practices to prevent mercury pollution.

"G": Gray Bag It – Discard amalgam wastes into a gray bag.

"R": Recycle It – Select a responsible dental amalgam recycler who can manage your waste amalgam safely from the list of recyclers below.

"I": Install It — Install an amalgam separator to capture up to 95% of the mercury going down the drain. This is the KEY to success.

"T": Teach It – Educate and train staff about the proper management of dental amalgam.

See the box below for a list of these facilities; the American Dental Association also has a <u>directory</u> of dental waste recyclers (PDF).

Facilities Permitted under the Resource Conservation and Recovery Act (RCRA) to Accept Dental Amalgam Waste

Drawing upon information received from recovery facilities related to their 2007 RCRA Biennial Report forms, EPA has compiled the following list of RCRA-permitted mercury retorters that accept dental amalgam waste.

PLEASE NOTE: This list is based upon information submitted directly by the facilities and is for informational purposes only. The list may not be comprehensive or up-to-date. For additional information, please contact your state hazardous waste authority. Inclusion on the list does not confer any rights or benefits, nor does it imply any governmental sanction or endorsement whatsoever by the U.S. EPA or the federal government.

Bethlehem Apparatus Company, Inc. 890 Front Street Hellertown, PA 18055 (610) 838-7034

Mercury Waste Solutions, Inc. 21211 Durand Avenue Union Grove, WI 53182 1-800-741-3343

Advanced Environmental Recycling Company, LLC (Corporate Office) 2591 Mitchell Avenue Allentown, PA 18103 1-866-447-5177

Veolia ES Technical Solutions, LLC (Corporate Office) 700 East Butterfield Road Suite 201 Lombard, IL 60148 (630) 218-1763

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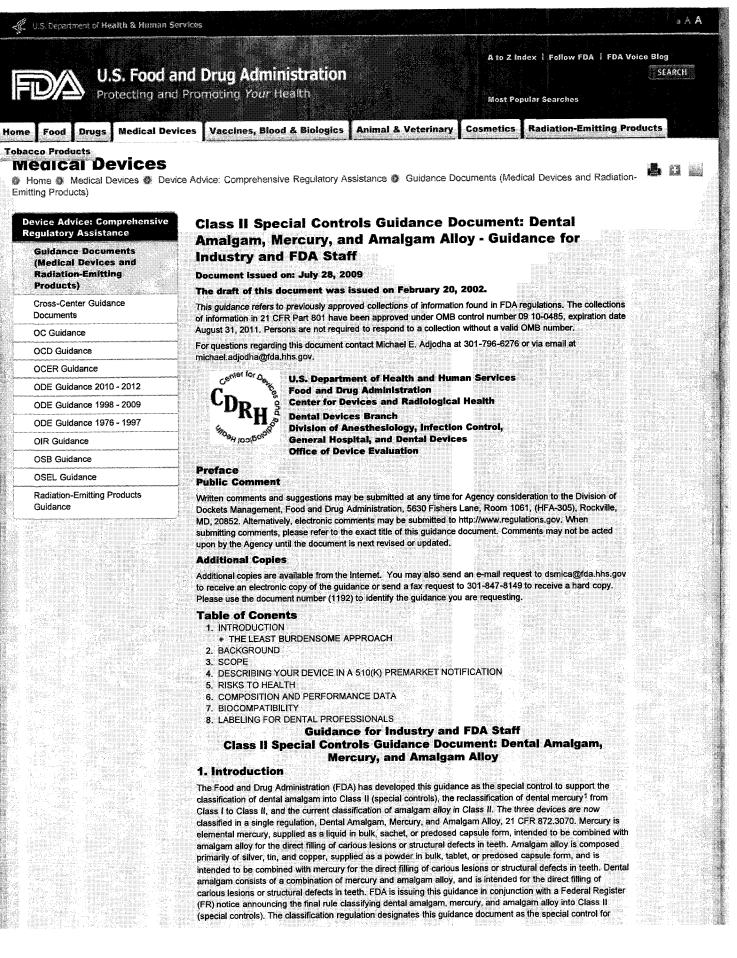
EPA Home | Privacy and Security Notice | Contact Us

http://www.epa.gov/mercury/dentalamalgam.html Print As-Is

Last updated on Wednesday, October 03, 2012

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EXHIBIT E



these three devices.

Designation of this document as a special control means that any firm currently marketing, or intending to market, dental amalgam, mercury, or amalgam alloy will need to address the issues covered in this special controls guidance. The firm must show that its device addresses the issues of safety and effectiveness identified in this guidance, either by meeting the recommendations of this guidance or by some other means that provides equivalent assurances of safety and effectiveness.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/Overview /MedicalDeviceProvisionsofFDAModemizationAct/ ucm136685.htm

2. Background

A manufacturer who intends to market a device of this generic type must

- conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the act), including the premarket notification requirements described in 21 CFR 807 Subpart E,
- conform to the special control developed for this device by addressing the specific risks to health associated with dental amalgam devices identified in this guidance, and
- obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.81 and 807.87).

FDA believes that special controls, when combined with the general controls of the act, are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

This special control guidance identifies the classification regulation and product codes for dental amalgam, mercury, and amalgam alloy(Please refer to Section 3. Scope). Other sections of this guidance document provide recommendations to manufacturers on addressing risks related to these devices.

This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, the guidance entitled Format for Traditional and Abbreviated 510(k)s², and the Premarket Notification 510(k) section of CDRH's Device Advice web page.³

Under The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance,⁴ a manufacturer may submit a Traditional 510(k), an Abbreviated 510(k), or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA issues a Class II special controls guidance document for the device. Manufacturers considering certain modifications to their own cleared devices may lessen their regulatory burden by submitting a Special 510(k). For more information on types of Premarket Notification 510(k) of CDRH's Device Advice web page⁵.

3. Scope

The scope of this guidance is limited to the devices described below that are classified in 21 CFR 872.3070 and include the product codes listed in the table.

§ 872.3070 Dental Amalgam, Mercury, and Amalgam Alloy

(a) Identification. Dental amalgam is a device that consists of a combination of elemental mercury, supplied as a liquid in bulk, sachet, or predosed capsule form, and amalgam alloy composed primarily of silver, tin, and copper, supplied as a powder in bulk, tablet, or predosed capsule form, for the direct filling of carious lesions or structural defects in teeth. This device also includes the individual component devices, mercury and amalgam alloy, when intended to be combined with each other to form dental amalgam.

(b) Classification. Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy." See § 872.1(e) for the availability of this guidance document.

This generic type of device includes encapsulated dental amalgam, as well as its individual components mercury and amalgam alloy, which may be marketed individually in bulk, sachet, or tablet form.

Firms intending to market mercury or amalgam alloy separately will need to address the specific risks to health identified in this guidance for those devices.

The relevant FDA product codes for this classification are as follows:

Product Code	Description
oiv	Dental Amalgam
ELY	Mercury
EJJ	Amalgam Alloy

This generic type of device does not include the following:

dental amalgam capsule classified under 21 CFR.872.3110

- mercury and alloy dispenser classified under 21 CFR 872.3080
- Idental amalgamator classified under 21 CFR 872.3100
- base metal alloys classified under 21 CFR 872.3710, and
- noble metal alloys classified under 21 CFR 872.3060.
- 4. Describing Your Device in a 510(k) Premarket Notification

FDA recommends that, when submitting a 510(k) premarket notification, you identify your device by regulation and product code as described in Section 3 and include the information discussed below.

FDA recommends that you compare your device to a legally marketed predicate device and that you provide information to show how your device is both similar to, and different from, the predicate device. Side by side comparisons, whenever possible, are desirable; for example, using a tabular format as shown below. We also recommend that you describe how any differences may affect the comparative safety or effectiveness of your device.

Table 1: Comparison of Your Device and Predicate Device

Descriptive Information	Your Device	Predicate Device
Intended Use - including any specific indication for use		
Composition of Materials – the chemical composition of device		
Physical Properties – e.g., compressive strength, creep, dimensional change		
Differences –aspects of the device that are different from the predicate device		

5. Risks to Health⁶

In the table below, FDA has identified the potential risks to health generally associated with the use of dental amalgam devices that this special controls guidance is intended to address. The measures recommended to mitigate these risks are described in this guidance document, as shown in the table below. Before submitting your 510(k), you should conduct a risk analysis to identify any other risks specific to your device. You should describe the risk analysis method used and include the results of this analysis in your 510(k). If you elect to use an alternative approach to address a particular risk identified in this document, or have identified other risks in addition to those described in this document, you should provide sufficient detail to support the approach you have used to address those risks.

Table 2: Dental	Amalgam	Risks and	Recommended	Mitigation Measures
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Risks	Recommended Mitigation Measures
Exposure to Mercury	Section 8. Labeling Section 6. Performance Data (mercury vapor release)
Allergic Response Including Adverse Tissue Reaction	Section 7. Biocompatibility Section 8. Lab el ing
Contamination	Section 6. Composition and Performance Data
Mechanical Failure	Section 6. Composition and Performance Data Section 8. Labeling
Corrosion	Section 6. Composition and Performance Data Section 8. Labeling
Improper Use	Section 8. Labeling

Table 3: Mercury Risks and Recommended Mitigation Measures

Risks	Recommended Mitigation Measures
Exposure to Mercury	Section 8. Labeling
Contamination	Section 6. Composition and Performance Data
Improper Use	Section 8. Labeling

Table 4: Amalgam Alloy Risks and Recommended Mitigation Measures

Risks	Recommended Mitigation Measures
Allergic Response Including Adverse Tissue Reaction	Section 7. Biocompatibility Section 8. Labeling
Mechanical Failure	Section 6. Composition and Performance Data Section 8. Labeling
Corrosion	Section 6. Composition and Performance Data Section 8. Labeling
Improper Use	Section 8. Labeling

6. Composition and Performance Data

FDA recommends that you evaluate your dental amalgam, mercury, and amalgam alloy devices using the relevant portions of the FDA-recognized standard listed below or an equivalent method:

ISO 24234:2004(E), Dentistry-Mercury and alloys for dental amalgam.

For amalgam alloy and dental amalgam, we recommend that the testing be performed on the finished form⁷ of the device, i.e., dental amalgam, the combination of mercury and amalgam alloy.

For mercury and dental amalgam, we recommend that the composition be free from contamination as specified by ISO 24234:2004(E).

A. Chemical Composition

FDA recommends that you provide the complete chemical composition of your dental amalgam, mercury, and amalgam alloy devices, totaling 100 percent by mass, and the Chemical Abstracts Service⁸ (CAS®) registry number of all constituents of the formulation.

B. Performance Data

FDA recommends that you provide the following performance data for your mercury⁹ device:

visual assessment that mercury is free from contamination, as specified by ISO 24234:2004(E).

FDA recommends that you provide the following physical properties of your dental amalgam and amalgam alloy¹⁰ devices:

- compressive strength (MPa) @ 1 hr
- compressive strength (MPa) @ 24 hrs
- maximum creep (%)
- dimensional change during hardening (%)
- * particle size distribution (μ) and shape, i.e., spherical, irregular, etc.
- corrosion products¹¹ identifying the ions leached (µg/cm²) and mercury vapor released during corrosion (ng/cm² in 4 hrs)
- trituration time (s)
- working time (min)

7. Biocompatibility

FDA recommends that you conduct biocompatibility testing for your dental amalgam device on the finished form¹², i.e., the combined product of mercury and amalgam alloy, as described in the following FDA-recognized standard, or by an equivalent method:

ISO 7405:1997(E), Dentistry - Preclinical evaluation of biocompatibility of medical devices used in dentistry—Test methods for dental materials.

If the composition of your dental amalgam device has already been demonstrated to be biocompatible for the same indication and the same type of tissue contact, either by a predicate device or in the literature, you may support the biocompatibility of your device by identifying the predicate or citing to the literature, in lieu of performing biocompatibility testing. However, if your device contains new chemical components or additives, or uses new technology, you should conduct biocompatibility testing, as described above.

8. Labeling for Dental Professionals¹³

FDA recommends that the labeling of your dental amalgam, mercury, and amalgam alloy devices include information sufficient to inform dental professionals of the properties and proper use of the devices. This information should include the device's composition, including its mercury content, physical properties, warnings, precautions, and information for use as described below.

A. Composition

FDA recommends that the labeling of your dental amalgam, mercury, and amalgam alloy devices identify and provide the mass fraction of every element of the device, including mercury, that is present in a concentration greater than 0.5%. The identity of other elements present in a concentration less than or equal to 0.5% may be disclosed without percentages. Disclosure of the mercury content should be stated clearly on the packaging of the device. The following statement is recommended:

- * Contains []% mercury by weight
- **B.** Physical Properties

FDA recommends that the labeling of your dental amalgam and amalgam alloy devices disclose the following physical properties:

- compressive strength (MPa) @ 24 hrs
- dimensional change during hardening (%)
- trituration time (s)
- working time (min)
- **C. Warnings**

FDA recommends that the labeling of your dental amalgam and mercury devices include the following warnings for health professionals about potential exposure to mercury:

- WARNING CONTAINS MERCURY
- may be harmful if vapors are inhaled
- **D.** Contraindication

FDA recommends that the labeling of your dental amalgam and mercury devices include the following contraindication:

* do not use in persons with a known mercury allergy

E. Precautions

FDA recommends that the labeling of your dental amalgam, mercury, and amalgam alloy devices include the following precautions regarding use of the devices:

- * do not place the device in direct contact with other types of metals
- use with adequate ventilation
- single-use only
- store in a cool, well ventilated place
- F. Information for Use

Dental amalgam has been and remains one of the most commonly used restorative materials in dentistry. Although amalgam has been used successfully for many years, the risks associated with this device have been controversial. In order for dentists to make appropriate treatment decisions with their patients, it is important to provide information to help dentists understand the complexities of the science related to dental amalgam and its mercury content.

FDA recommends that the labeling of your dental amalgam, mercury, and amalgam alloy devices include the following statement regarding use of the devices, and that dental professionals consider this information when developing individual treatment recommendations:

"Dental amalgam has been demonstrated to be an effective restorative material that has benefits in terms of strength, marginal integrity, suitability for large occlusal surfaces, and durability.¹⁴ Dental amalgam also releases low levels of mercury vapor, a chemical that at high exposure levels is well-documented to cause neurological and renal adverse health effects.¹⁵ Mercury vapor concentrations are highest immediately after placement and removal of dental amalgam but decline thereafter.

Clinical studies have not established a causal link between dental amalgam and adverse health effects in adults and children age six and older. In addition, two clinical trials in children aged six and older did not find neurological or renal injury associated with amalgam use.¹⁶

The developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor. Very limited to no clinical information is available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed.

The Agency for Toxic Substances and Disease Registry's (ATSDR) and the Environmental Protection Agency (EPA) have established levels of exposure for mercury vapor that are intended to be highly protective against adverse health effects, including for sensitive subpopulations such as pregnant women and their developing fetuses, breastfed infants, and children under age six.¹⁷ Exceeding these levels does not necessarily mean that any adverse effects will occur.

FDA has found that scientific studies using the most reliable methods have shown that dental amalgam exposes adults to amounts of elemental mercury vapor below or approximately equivalent to the protective levels of exposure identified by ATSDR and EPA. Based on these findings and the clinical data, FDA has concluded that exposures to mercury vapor from dental amalgam do not put individuals age six and older at risk for mercury-associated adverse health effects.

Taking into account factors such as the number and size of teeth and respiratory volumes and rates, FDA estimates that the estimated daily dose of mercury in children under age six with dental amalgams is lower than the estimated daily adult dose. The exposures to children would therefore be lower than the protective levels of exposure identified by ATSDR and EPA.

In addition, the estimated concentration of mercury in breast milk attributable to dental amalgam is an order of magnitude below the EPA protective reference dose for oral exposure to inorganic mercury. FDA has concluded that the existing data support a finding that infants are not at risk for adverse health effects from the breast milk of women exposed to mercury vapors from dental amalgam."

¹ FDA is no longer using the term "dental mercury," but instead is using "mercury," to more accurately reflect the fact that the mercury used in dental amalgam is elemental mercury.

² http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/GuidanceDocuments/ ucm084365.htm

³ http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/HowtoMarketYourDevice/ PremarketSubmissions/PremarketNotification510k/default.htm

4 http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/GuidanceDocuments/ ucm080187.htm

⁵ http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/HowtoMarketYourDevice/ PremarketSubmissions/PremarketNotification510k/default.htm

⁶ The preamble to the final rule describes in detail the risks to health presented by this device that FDA has identified and explains how the recommendations in this guidance address those risks.

⁷ The finished form is to be tested because mercury and amalgam alloy are not used alone but must be combined to form dental amalgam.

⁸ http://www.cas.org/expertise/cascontent/registry/index.html

⁹ This includes dental amalgam when provided in encapsulated form.

¹⁰ The physical properties of amalgam alloy are to determined from those of dental amalgam, the finished form.

¹¹ See Annex A, Determination of Immersion Corrosion for Dental Amalgam, of ISO 24234:2004(E)

¹² Preclinical evaluation of the finished form is a useful measure of biocompatibility, whereas such testing of individual device components, mercury or amalgam alloy, is not.

¹³ Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

¹⁴ Dental Amalgam: A Scientific Review and Recommended Public Health Service Strategy for Research, Education and Regulation; Public Health Service, U.S. Department of Health and Human Services, January 1993.

¹⁵ Liu, J. et al., "Toxic effects of metals," <u>Casarett & Doull's Toxicology: The Basic Science of Poisons</u>, Chapter 23, pp. 931-979, McGraw-Hill Medical, New York, New York, 2008.

Clarkson, T.W. et al., "The Toxicology of Mercury and Its Chemical Compounds," <u>Critical Reviews in</u> <u>Toxicology</u>, Vol. 36, pp. 609-662, 2006.

¹⁶ De Rouen, T. et al., "Neurobehavioral Effects of Dental Amalgam in Children, A Randomized Clinical Trial," Journal of the American Medical Association, Vol. 295, 1784-1792, No. 15, April, 19, 2006.

Bellinger, D.C. et al., "Neuropsychological and Renal Effects of Dental Amalgam in Children: A Randomized Clinical Trial," <u>Journal of the American Medical Association</u>, Vol. 295, No. 15, April 19, 2006, 1775-1783, 2006. Barregard, L. et al., "Renal Effects of Dental Amalgam in Children: The New England Children's Amalgam Trial," <u>Environmental Health Perspectives</u>, Volume 116, 394-399, No. 3, March 2008.

Woods, J.S. et al., "Biomarkers of Kidney Integrity in Children and Adolescents with Dental Amalgam Mercury Exposure: Findings from the Casa Pia Children's Amalgam Trial," <u>Environmental Research</u>, Vol. 108, pp. 393-399, 2008.

Lauterbach, M. et al., "Neurological Outcomes in Children with and Without Amalgam-Related Mercury Exposure: Seven Years of Longitudinal Observations in a Randomized Trial," <u>Journal of the American Dental</u>

