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


DIVISION OF
CORPORATION FINANCE

February 10, 2017

Andrea A. Robinson
Amgen Inc.
robinson@amgen.com

Re: Amgen Inc.
Incoming letter dated January 13, 2017

Dear Ms. Robinson:

This is in response to your letter dated January 13, 2017 concerning the shareholder proposal submitted to Amgen by Mercy Investment Services, Inc. et al. We also have received a letter on the proponents' behalf dated January 30, 2017. 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,

Matt S. McNair
Senior Special Counsel

Enclosure

cc: Paul M. Neuhauser
pmneuhauser@aol.com

February 10, 2017

**Response of the Office of Chief Counsel**
**Division of Corporation Finance**

Re: Amgen Inc.
Incoming letter dated January 13, 2017

The proposal requests that the board issue a report listing the rates of price increases year-to-year of the company's top ten selling branded prescription drugs between 2010 and 2016, including the rationale and criteria used for these price increases, and an assessment of the legislative, regulatory, reputational and financial risks they represent for the company.

There appears to be some basis for your view that Amgen may exclude the proposal under rule 14a-8(i)(7), as relating to Amgen's ordinary business operations. In this regard, we note that the proposal relates to the rationale and criteria for price increases of the company's top ten selling branded prescription drugs in the last six years. Accordingly, we will not recommend enforcement action to the Commission if Amgen 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 Amgen relies.

Sincerely,

Courtney Haseley
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 proposal 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 and rules administered by the Commission, including arguments as to whether or not activities proposed to be taken would violate 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 adversarial procedure.

It is important to note that the staff's no-action responses to Rule 14a-8(j) submissions reflect only informal views. The determinations reached in these no-action 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 company's management omit the proposal from the company's proxy materials.

# PAUL M. NEUHAUSER

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January 30, 2017

Securities & Exchange Commission
100 F Street, NE
Washington, D.C. 20549

Att: Matt McNair, Esq.
Special Counsel
Division of Corporation Finance

Via email to shareholderproposals@sec.gov

Re: Shareholder Proposal Submitted to Amgen Inc.

Dear Sir/Madam:

I have been asked by Mercy Investment Services, Inc., Trinity Health, Dignity Health, the Congregation of the Sisters of Charity of the Incarnate Word, San Antonio, the Benedictine Sisters of Mount St. Scholastica, the Benedictine Sisters of Monasterio Pan de Vida and Dana Investment Advisors, Inc. (hereinafter referred to jointly as the "Proponents"), each of which is the beneficial owner of shares of common stock of Amgen Inc. (hereinafter referred to either as "Amgen" or the "Company"), and who have jointly submitted a shareholder proposal to Amgen, to respond to the letter dated January 13, 2017, sent to the Securities & Exchange Commission by the Company, in which Amgen contends that the Proponents' shareholder proposal may be excluded from the Company's year 2017 proxy statement by virtue of Rules 14a-8(i)(7) and 14a-8(i)(10).

I have reviewed the Proponents' shareholder proposal, as well as the aforesaid letter sent by the Company, and based upon the foregoing, as well as upon a review of Rule 14a-8, it is my opinion that the Proponents' shareholder proposal must be included in Amgen's year 2017 proxy statement and that it is not excludable by virtue of either of the cited rules.

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The Proponents' shareholder proposal requests the Company to prepare a report delineating the rates of price increases of the Company's ten top selling drugs during the past several years, the "rationale and criteria" underlying any such price increases and an "assessment of the legislative, regulatory, reputational and financial risk" arising from any such increases.

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RULE 14a-8(i)(7)

There are some matters as to which there is no disagreement. These include that proposals dealing with the pricing of products normally are matters of "ordinary business". However, it is equally clear that proposals that deal with ordinary business matters, but which nevertheless raise significant policy issues for the registrant, may not be excluded under Rule 14a-8(i)(7). Release 34-12599 (Nov. 22, 1976); Release 34-40,018 (May, 21, 1998).

It is abundantly clear that the pricing of their drugs is a significant policy concern for drug manufacturers. It should not be necessary to rehearse this proposition for the Staff since they have already frequently so held. See, e.g., *Celgene Corp.* (March 19, 2015); *Vertex Pharmaceuticals Inc*. (Feb. 25, 2015); *Gilead Sciences, Inc.* (Feb. 23, 2015).

Since those letters, the significance of drug pricing as a policy matter for drug manufactures has only increased, with widespread public outrage; Congressional hearings re Valeant and Turing in February, 2016, where evidence showed increases of up to fifty times and where the former CEO of Turing took the Fifth Amendment (see New York Times articles of February 3, 2016: "Martin Shkreli All But Gloated Over Hugh Drug Price Increases, Memos Show" and February 5, 2016: "Martin Shkreli Invokes the Fifth Amendment During Grilling by Congress"; and the more recent EpiPen pricing scandal . (See, e.g., New York Times article of September 21, 2016: "Mylan's Chief is chastised by Lawmakers Questioning EpiPen Pricing".) Even more recently, President Trump said that the

pharmaceutical companies were "getting away with murder" and vowed that the Federal government would negotiate drug prices. (New York Times article of January 11, 2017: "Trump Says Pharma 'Getting Away With Murder', Stocks Slide". Most recently, an article by Gretchen Morgenson in the Sunday Business Section of the New York Times of January 29, 2017 entitled "$38,000 Drug, Missing Dose of Disclosure" described the pricing of a drug that had, over the course of a few years, increased in price from $40 per vial to $38,000 per vial, an increase of close to a thousand times.

The various letters cited by the Company in the first and third paragraphs on page 3 of its letter are inapposite. They concern proposals unrelated to drug pricing and that raised no significant policy issue whatsoever for the registrant.

The two proposals discussed in paragraph two on page 3 were, indeed, submitted to drug companies. In both instances, however, the Staff no-action letters are readily distinguishable. In *UnitedHealth Group Inc*. (March 16, 2011) the registrant argued that the proposal could be excluded under (i)(7) for any of three reasons, including that it related to "the pricing of its products". Another ground that the registrant argued was that it related to the registrant's "management of . . . expenditures". The Staff excluded the proposal, but not on the ground that it related to the pricing of its products, but rather, as stated in the Staff's letter, on the ground that "the proposal relates to the manner in which the company manages its expenses". The *UnitedHealth* letter therefore provides no support whatsoever to the Company's argument that the Proponent's shareholder proposal should be excluded by Rule 14a-8(i)(7).

The *Johnson & Johnson* letter provides even less support. That letter is dated January 12, 2004 and the registrant argued that it was a "marketing" proposal. The Staff agreed. The date of the Staff letter is also notable. Not only was it prior to the current intense furor over drug pricing, it was also decided at a time when "risk" proposals were automatically excluded. The *Johnson & Johnson* letter was certainly of that ilk since it asked "how our company will respond to rising regulatory, legislative and public pressure" over drug pricing. However, since the date of that letter, the Staff's approach to risk proposals has been changed (see SLB 14E (October 27, 2009)) and risk proposals are no longer automatically excluded. As the Staff there stated, it would change its approach since in the past its analytical approach "may have resulted in the unwarranted exclusion of proposals that relate to the evaluation of risk but that focus on significant policy issues".

The Company attempts to avoid the clear Staff decisions that state that drug pricing is a significant policy issue for drug manufacturers by claiming that the instant proposal does not focus on "restraining or containing prices with the goal of providing affordable access to prescription drugs" (See first two lines at top of page 4 of the Company's letter.) This is, indeed, a strange reading of a proposal asking for the "rationale and criteria" for price increases and "an assessment of the legislative, regulatory, reputational and financial risks" of price increases. It is true that the proposal also asks for examples of how those "rationale and criteria" have actually been applied by the Company, but such an asking does not alter the primary focus of the proposal on "restraining or containing prices with the goal of providing affordable access to prescription drugs". Indeed, the Proponents' shareholder proposal is focused exclusively on Amgen's fundamental business strategy.

Finally, the Company attempts to argue that the proposal "micromanages" the Company's business. It is true that the proposal requests disclosure of certain data, namely the *rate* of price increase for its top selling drugs. This is not too intricate a matter for shareholders to understand. Note that it is the *rate* of increase that is being requested, not the actual prices charged. Indeed, the proposal "micromanages" significantly less than the proposals that were deemed not to micromanage in *Celgene Corp* (March 9, 2015), *Vertex Pharmaceuticals Inc*. (February 25, 2015) and *Gilead Sciences, Inc*. (February 23, 2015), each of which is cited at the top of page 4 of the Company's letter. In each of those letters the proposal read as follows:

> "RESOLVED, that shareholders [request the Company to report . . . on the risks to [the Company] from rising pressure to contain U.S. specialty [i.e. those costing more than $600 per month] drug prices. . . . The report should address [the Company]'s response to risks created by:
>
> The relationship between [the Company]'s specialty drug prices and each of clinical benefit, patient access, the efficacy and price of alternative therapies, drug development costs and the proportion of those costs borne by academic institutions, foundations or the government;
>
> Price disparities between the U.S. and other countries and public concern that U.S. patients and payers are shouldering an excessive proportion of the cost burden; and
>
> Price sensitivity of prescribers, payers and patients. "

. [In the Gilead and Celgene proposal was added:] The possibility that pharmacoeconomics techniques such as cost-effectiveness studies will be relied on more by payers in making specialty drug reimbursement decisions.

It is clear beyond cavil that the Proponents' shareholder proposal is far less intrusive, involves far less detail, probes far less deeply into matters of a complex nature. and is far more within the competency of shareholders to evaluate, than was the case with respect to the proposals in in the *Celgene, Gilead* and *Vertex* letters.

Nor do the various Staff letters cited in the aforesaid page 4 paragraph provide even a scintilla of support for the Company's position. References to risks, such as "legislative, regulatory, reputational and financial", no longer result in the automatic exclusion of a shareholder proposal under Rule 14a-8(i)(7). SLB 14E (October 27, 2009). Rather exclusion depends on whether the evaluation of risk focuses on a significant policy issue for the registrant, as it clearly does in the instant case. The *Amazon* letter dealt with a proposal that focused on a topic that the Staff has consistently held *not* to raise a significant policy issue *for the registrant*, which was a retailer, even though the product might raise a significant policy issue for the manufacturer. It is therefore not relevant to the instant situation.

As for the remaining letters, the *Pet Smart* letter dealt with legal compliance, a topic routinely excluded under Rule 14a-8 (i)(7); the *CIGNA* proposal involved expense management and the *Capital One* proposal asked for information about how the registrant managed its workforce. Each of these letters was properly excluded because the proposal in each case dealt with matters *in addition* to a significant policy matter. This is not so in the instant case, where the Proponents' shareholder proposal deals exclusively with drug pricing, a significant policy issue for Amgen.

In short, it is clear beyond any doubt, reasonable or otherwise, that the Proponents' shareholder proposal does not involve micromanaging, but rather the proposal focuses on Amgen's fundamental business strategy with respect to its pricing policies for pharmaceutical products

For the foregoing reasons, the Company has failed to carry its burden of proving that the Proponents' shareholder proposal is excludable by virtue of Rule 14a-8(i)(7)

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RULE 14a-8(i)(10)

The Company claims that it "already provides disclosure regarding the criteria used for drug price *increases* . . . and such disclosure is available on [its website]. (See opening of first full paragraph, page 6 of its letter; emphasis supplied.) Unfortunately, no such disclosure is available on the website. Nine pages of screenshots have been provided to establish Amgen's claim. The first four screenshots describe a reimbursement program for which a few patients may be eligible and the limited availability of experimental drugs. Nothing on those three pages even remotely addresses how the Company sets the price of its drugs or the" rationale and criteria" it uses in deciding how to price its drugs, no less the "rationale and criteria" that it uses in deciding when to *increase* those prices. Nor do these four pages attempt to assess, in any manner, shape or form, the risks to the Company that may arise from unwarranted price increases.

The next two screenshots, pages 5 and 6, entitled "Drug Costs in Perspective" and "The Real Value of Innovative Medicine", are concerned almost exclusively with general societal information and trends (e.g. that cardiovascular disease is responsible for one third of deaths). At the bottom of page 6 is a section entitled "So What Are We Doing", the title of which can easily be read. However, the six bullet points beneath the heading cannot be read at a normal computer setting. If the settings are increased to 200% or 400%, some, but not all, can be deciphered. But it is not worth it, since they are simply hackneyed bromides. First: "Evolve manufacturing to bring costs down through innovation"; Second: "[Undecipherable] up and reduce cost of bringing new innovative drugs to market". These bullet points, even if one were (erroneously) to deem them qualified as disclosure in light of their unreadability, do not address the requests set forth in the Proponents' shareholder proposal.

At the bottom of page 5, is a heading (in smaller print than the one on page 6) with the more promising title (if you can read it) of "How we price our medicines". However, the four bullet points are essentially unreadable, even at 2 or 4 times magnification. They appear to say:

*Are based on value (?) brought to patients, providers, payers and society
*Align with [five words undecipherable] that we undertake.
*Fund continued scientific innovation and insure access to our prescriptions (?)
*[Undecipherable] affordability and availability of patient [undecipherable] programs

Again, these bullet points, even if one were (erroneously) to deem them qualified as disclosure in light of their unreadability, are vague generalizations and do not even remotely address the requests set forth in the Proponents' shareholder proposal which is to provide the rationale and criteria for drug price *increases* at many multiple times the rate of inflation. Nor do they address, in any manner, shape or form, the risks to the Company that may arise from unwarranted price increases.

Screenshot pages 8 and 9 are entitled "The Value of Our Medicines". The principal item on page 8 is the box about how critical innovation is to the development of Amgen's medicines. Bullets include providing "cost-effective solutions"; "evolving manufacturing processes to drive down costs"; develop "new technologies"; "foster partnerships"; use "clinical trial efficiencies"; and be a "leading manufacturer" of drugs. Not much useful there. However, if one reads carefully, obscurely tucked away and lacking in equal prominence is a paragraph concerning the Company's drug pricing philosophy, namely that it should "reflect the "holistic economic value" it provides as well as the "unmet medical need, the size of the patient population" as well as "be aligned with the investment and risk". Assuming that an interested observer can find this rather obscure paragraph, lost among the nine pages of screenshots, it still addresses neither the rational nor the criteria for drug price *increases* multiple times the rate of inflation, nor does it address risk arising from such price increases.

We can also dismiss page 9 which appears to consist of links, primarily to a panel discussion at which a senior vice president of Amgen's basic point is that "just a focus on the price of these innovations is missing the bigger picture" which is their overall benefit to society. Apparently, the controversies over drug pricing simply miss the point. He does not address the "rationale and criteria" for drug price increases, but instead recites some of the usual bromides about how the Company tries to innovate in the costs of manufacturing; how it is investigating the molecular and generic basis of diseases; and that it works on patient engagement as well as on collaborative partnerships.

Finally, screenshot page 7 is entitled "The Price of Our Medicines", and is really the only place, hidden in the nine pages of screenshots, where pricing is attempted to be addressed. On that page, two separate sets of bullet points are set forth, but the second set appears to be directed at pricing in foreign countries, including those with socialized medicine. (See introduction to this set of bullet points saying that they set forth "factors in each country".) Thus, in all of the materials supplied by the company the only information that is arguably applicable

to the request made by the Proponents' shareholder proposal are the five bullet points in the second paragraph of screenshot 7. However, those five short phrases do not substantially implement the Proponents' proposal for the "rationale and criteria" for INCREASES in drug prices. The web pages make absolutely no attempt to explain the rationale for INCREASES in drug prices, since each and every one of the five factors listed (such as "value to society", "clinical benefits and medical costs avoided", "enables access to medicines", "competitive landscape" and "investment to fund scientific innovation") would seem to suggest factors to be used in setting an initial price for a new drug or, perhaps, factors to be considered in decreasing drug prices (e.g. competitive landscape). In short, nothing on this web page, or any other web page, pertains to criteria used by the Company when it INCREASES drug prices.

And, of course, the Company makes no argument whatsoever that it has supplied the specific data requested on the rate of the price increases of its products.

Nor has the Company responded to the request for an assessment of risks. Amgen claims that such an assessment is to be found in its most recent 10-K. Yet no specific quotation or citation to any such assessment is made by the Company. This is hardly surprising, since an examination of the 10-K reveals that nothing whatsoever pertaining to the assessment requested by the Proponents' shareholder proposal has been provided. A careful examination of the twelve pages devoted to the Company's response to Item 1A of Part II fails to uncover anything pertaining to risks arising from price *increases*. Not even a scintilla. The topic is never mentioned or referred to. Similarly, the March 31, 2016, 10-Q makes no references to the public outcry about price increases, merely reiterating the language from the 10-K that "public scrutiny of the price of drugs and other healthcare costs is *increasing and more control over pricing could hurt our ability to price our products"* while adding that there have been proposals (not enacted) that state agencies be able to cap prices. Neither reference constitutes a discussion of the risks arising from price increases, which are never mentioned. The September, 30, 2016, 10-Q does actually make a reference to price increases by altering the above quote to read: "public scrutiny of the price of drugs and other healthcare costs *is increasing and focus on pricing and price increases may limit our ability to set or increase the price of our products . . . which could have a material adverse effect on our product sales, business and results of operations.* (Italics added in both quotes to facilitate comparison.) Thus, price increases are now actually mentioned. Twice. In addition, the September 10-Q retains the discussion of possible state price caps and adds that a Vermont statute permits the

state to require justification from the manufacturer for certain types of price increases of certain drugs purchased by the state. Thus, the September 30 10-K has merely added the words “and price increases” and “”or increase the price” to its existing wording concerning general restraints on its ability to price its products; added a reference to a Vermont statute; and added the obvious observation that a focus on pricing and price increases could adversely affect the Company (instead of saying that such public scrutiny could “hurt our ability to price our products”). We do not believe that these passing references can possible be deemed to substantially implement a request to “*assess* the legislative, regulatory, reputational and financial risks” created by the exploding increases in prices for existing drugs.

In summary, although the Company on screenshot 7 talks a wee bit about pricing, that discussion is silent on the question of the “rationale and criteria” for prices INCREASES; there is no attempt whatsoever made to supply the requested data on the rates at which prices have increased; and risks arising from price increases are discussed nowhere in Amgen’s 10-K or in its March 10-Qs and in its September 10-Q only by adding a small handful of words. This meager performance cannot possibly be substantial implementation of the Proponents’ shareholder proposal.

Finally, the Company claims (final full paragraph, page 7 of its letter) that disclosure of the rationale and criteria for price increases and an assessment of risks arising from such increases “would result in disclosure of the Company’s proprietary information”. Yet the Company asserts that it has already” substantially implemented” this request. Both assertions cannot possibly be true simultaneously.

For the foregoing reasons, the Company has failed to carry its burden of proving that the Proponents shareholder proposal is excludable by virtue of Rule 14a-8(i)(10).

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In conclusion, we request that the Staff inform the Company that the SEC Proxy Rules require denial of the Company’s no-action letter request. We would appreciate your telephoning the undersigned at 941-349-6164 with respect to any questions in connection with this matter or if the Staff wishes any further

information.  Faxes can be received at the same number and mail and email addresses appear on the letterhead.

Very truly yours,

Paul M. Neuhauser

cc: Andrea A. Robinson
All proponents
Josh Zinner

Andrea A. Robinson
Associate General Counsel

AMGEN

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January 13, 2017

**VIA ELECTRONIC MAIL**

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Chief Counsel
100 F Street, N.E.
Washington, D.C. 20549
E-mail: shareholderproposals@sec.gov

**Re: Amgen Inc. Stockholder Proposal from Mercy Investment Services**

Ladies and Gentlemen:

Amgen Inc., a Delaware corporation (the "Company"), is filing this letter pursuant to Rule 14a-8(j) under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), to notify the Staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") of the Company's intention to exclude from the Company's proxy statement and form of proxy for the Company's 2017 Annual Meeting of Stockholders (the "2017 Proxy Materials") a stockholder proposal and supporting statement (the "Proposal") received from Mercy Investment Services and co-filers[1] (each a "Proponent" and, collectively, the "Proponents"), which relates to the commissioning of a report including the rationale and criteria used for year-to-year price increases of certain of the Company's branded prescription drugs, and an assessment of the risks related to such price increases. The Company respectfully requests confirmation that the Staff will not recommend enforcement action to the Commission if the Company excludes the Proposal on the following grounds:

(i) pursuant to Rule 14a-8(i)(7), as the Proposal relates to the Company's ordinary business operations; and

(ii) pursuant to Rule 14a-8(i)(10), as the Proposal has been substantially implemented.

Pursuant to Staff Legal Bulletin 14D (November 7, 2008), the Company is transmitting this letter by electronic mail to the Staff at shareholderproposals@sec.gov. The Company is also sending copies of this letter concurrently to each of the Proponents. Pursuant to Rule 14a-8(j), this

[1] The following entities have co-filed the Proposal: Trinity Health, Dana Investment Advisors, Inc., Dignity Health, Congregation of the Sisters of Charity of the Incarnate Word, San Antonio, Benedictine Sisters of Mount St. Scholastica, Benedictine Sisters of Monasterio Pan de Vida, and Sisters of St. Francis Charitable Trust.

letter is being submitted not less than 80 days before the Company intends to file its definitive 2017 Proxy Materials with the Commission.

## I. THE PROPOSAL

The Proposal, entitled "Disclose Criteria Used for Price Increases on Top Ten Drugs," requests that the Company's stockholders approve the following resolution:

> **RESOLVED**: Shareholders request the Board of Directors issue a report by November 1, 2017, at reasonable expense and excluding proprietary information, listing the rates of price increases year-to-year of our company's top ten selling branded prescription drugs between 2010 and 2016, including the rationale and criteria used for these price increases, and an assessment of the legislative, regulatory, reputational and financial risks they represent for our company.

A copy of the Proposal and supporting statement, which were received by the Company on October 18, 2016, are attached to this letter as Exhibit A.

## II. GROUNDS FOR EXCLUSION

We hereby respectfully request that the Staff concur with the Company's view that the Proposal may be excluded from the 2017 Proxy Materials for the reasons set forth below.

### A. The Proposal May be Excluded Pursuant to Rule 14a-8(i)(7) Because the Proposal Deals with Matters Relating to the Company's Ordinary Business Operations.

Under Rule 14a-8(i)(7), a company may exclude a stockholder proposal from its proxy materials if "the proposal deals with a matter relating to the company's ordinary business operations." The Commission has stated that the "general underlying policy of this exclusion is consistent with the policy of most state corporate laws: to confine the resolution of ordinary business problems to management and the board of directors, since it is impracticable for shareholders to decide how to solve such problems at an annual shareholders meeting." Exchange Act Release No. 34-40018 (May 21, 1998) ("1998 Release").

A stockholder proposal is considered "ordinary business" when (i) it relates to matters that "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"; or (ii) it "seeks to 'micro-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." 1998 Release. The Staff has also given guidance as to when a proposal requesting the preparation of a report is excludable under 14a-8(i)(7), stating that it may be excludable "if the subject matter of the special report . . . involves a matter of ordinary business." Exchange Act Release No. 34-20091 (Aug. 16, 1983) ("1983 Release"); *Duke Energy Corp.* (Feb. 24, 2012); *PepsiCo* (Mar. 3, 2011); *FedEx Corp.* (July 14, 2009); *The Coca-Cola Co.* (Jan. 21, 2009).

The Staff has consistently permitted exclusion of stockholder proposals under Rule 14a-8(i)(7) when those proposals relate to how a company makes specific pricing decisions regarding certain of its products. *See, e.g.*, *Equity LifeStyle Properties, Inc.* (Feb. 6, 2013) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on, among other things, "the reputational risks associated with the setting of unfair, inequitable and excessive rent increases that cause undue hardship to older homeowners on fixed incomes" and "potential negative feedback stated directly to potential customers from current residents," noting that the "setting of prices for products and services is fundamental to management's ability to run a company on a day-to-day basis"); *Western Union Co.* (Mar. 7, 2007) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board review, among other things, the effect of the company's remittance practices on the communities served and compare the company's fees, exchange rates, and pricing structures with other companies in its industry, noting that the proposal related to the company's "ordinary business operations (i.e., the prices charged by the company)").

The Staff has also permitted exclusion of proposals under Rule 14a-8(i)(7) requesting reports on how companies intend to respond to particular regulatory, legislative and public pressures relating to pricing policies or price increases. *See UnitedHealth Group Inc.* (Mar. 16, 2011) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a board report on how the company is responding to regulatory, legislative, and public pressures to ensure affordable health care coverage and the measures the company is taking to contain price increases of health insurance premiums as relating to the company's ordinary business operations); *Johnson & Johnson* (Jan. 12, 2004) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board review pricing and marketing policies and prepare a report on how the company will respond to regulatory, legislative and public pressure to increase access to prescription drugs as relating to the company's ordinary business operations).

In addition, the Staff has permitted exclusion of proposals under Rule 14a-8(i)(7) where proponents sought to direct specific pricing policies. *See, e.g.*, *Host Hotels & Resorts, Inc.* (Feb. 6, 2014) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board consider providing senior citizens and stockholders discounts on hotel rates, noting that discount pricing policy determinations is an ordinary business matter); *Ford Motor Co.* (Jan. 31, 2011) (permitting exclusion under Rule 14a-8(i)(7) of a proposal seeking to allow stockholders who purchased a new vehicle and "had no spare tire and hardware for mounting [the spare tire to] . . . be able to purchase same from Ford Motor at the manufacturing cost of same," noting that "the setting of prices for products and services is fundamental to management's ability to run a company on a day-to-day basis"); *MGM Mirage* (Mar. 6, 2009) (permitting exclusion under Rule 14a-8(i)(7) of a proposal urging the board to implement a discount dining program for local residents, noting that the proposal related to the company's "ordinary business operations (i.e., discount pricing policies)").

The Company understands that, under limited circumstances, the Staff has declined to permit the exclusion of proposals relating to the pricing policies for drug products. In each of those instances, however, the proposal focused on the fundamental business strategy of the company with respect to its pricing policies rather than on how and why the company makes specific pricing decisions regarding certain of those products. In particular, the request in each of

those proposals appeared to focus on restraining or containing prices with the goal of providing affordable access to prescription drugs. *See Celgene Corp.* (Mar. 19, 2015) (declining to permit exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on the risks to the company from rising pressure to contain U.S. specialty drug prices, noting that the proposal focused on the company's "fundamental business strategy with respect to its pricing policies for pharmaceutical products"); *Vertex Pharmaceuticals Inc.* (Feb. 25, 2015) (same); *Gilead Sciences, Inc.* (Feb. 23, 2015) (same); *Bristol-Myers Squibb Co.* (Feb. 21, 2000) (declining to permit exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board create and implement a policy of price restraint on pharmaceutical products for individual customers and institutional purchasers to keep drug prices at reasonable levels and report to stockholders any changes in its pricing policies and procedures, noting that the proposal related to the company's "fundamental business strategy, i.e., its pricing for pharmaceutical products"); *Warner-Lambert Co.* (Feb. 21, 2000) (same); *Eli Lilly and Co.* (Feb. 25, 1993) (declining to permit exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company "seek input on its pricing policy from consumer groups, and to adopt a policy of price restraint," noting that the proposal related to "the [c]ompany's fundamental business strategy with respect to its pricing policy for pharmaceutical products").

Here, the Proposal delves deeply into the Company's day-to-day operations by mandating disclosure of "the rationale and criteria used" by the Company's management in making product-specific and time-period-specific price increase determinations. The Proposal also mandates an "assessment of the legislative, regulatory, reputational and financial risks" associated with these decisions. The supporting statement further requests that the Company provide "detailed justification for price increases."

These mandates demonstrate that the Proposal is seeking to probe deeply into matters of a complex nature upon which stockholders, as a group, are not in a position to make an informed judgment. The "rationale and criteria" used by management to make pricing decisions are matters that are fundamental to management's ability to run the Company on a day-to-day basis, and of the type that, as a practical matter, should not be subject to direct stockholder oversight. Furthermore, these are not matters relating to a more general notion of fundamental business strategy. Because the Proposal both seeks to probe too deeply into matters of a complex nature and subject to stockholder oversight matters that are fundamental to management's ability to run the Company on a day-to-day basis, and because the Proposal does not solely focus on the Company's fundamental business strategy, the Proposal is excludable under Rule 14a-8(i)(7) because it relates to the Company's ordinary business operations.

The Company notes that a proposal may not be excluded under Rule 14a-8(i)(7) if it is determined to focus on a significant policy issue. However, the fact that a proposal may touch upon a significant policy issue does not preclude exclusion under Rule 14a-8(i)(7). Instead, the question is whether the proposal focuses primarily on a matter of broad public policy versus matters related to the company's ordinary business operations. *See* 1998 Release and Staff Legal Bulletin 14E (Oct. 27, 2009).

The Staff has consistently permitted exclusion of stockholder proposals under Rule 14a-8(i)(7) where the proposal focused on ordinary business matters, even though it also related to a

potential significant policy issue. For example, in *Amazon.com, Inc.* (Mar. 27, 2015), the Staff permitted exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company "disclose to shareholders reputational and financial risks it may face as a result of negative public opinion pertaining to the treatment of animals used to produce products it sells" where the proponent argued that Amazon's sale of foie gras implicated a significant policy issue (animal cruelty). In granting no-action relief, the Staff determined that "the proposal relate[d] to the products and services offered for sale by the company." Similarly, in *PetSmart, Inc.* (Mar. 24, 2011), the Staff permitted exclusion under Rule 14a-8(i)(7) of a proposal calling for suppliers to certify that they have not violated certain laws regarding the humane treatment of animals, even though the Staff had determined that the humane treatment of animals was a significant policy issue. In its no-action letter, the Staff specifically noted the company's view that the scope of the laws covered by the proposal were "fairly broad in nature from serious violations such as animal abuse to violations of administrative matters such as record keeping." *See also, e.g., CIGNA Corp.* (Feb. 23, 2011) (permitting exclusion under Rule 14a-8(i)(7) where, although a proposal addressed the potential significant policy issue of access to affordable health care, it also asked CIGNA to report on expense management, an ordinary business matter); *Capital One Financial Corp.* (Feb. 3, 2005) (permitting exclusion under Rule 14a-8(i)(7) where, although a proposal addressed the significant policy issue of outsourcing, it also asked the company to disclose information about how it manages its workforce, an ordinary business matter).

In this instance, even if the Proposal were to touch on a potential significant policy issue, similar to the precedent above, the Proposal's request focuses on how and why the Company makes specific pricing decisions regarding certain of its products, which are ordinary business matters that are fundamental to management's ability to run the Company on a day-to-day basis. Accordingly, and consistent with the precedent described above, the Company believes that the Proposal may be excluded from its 2017 Proxy Materials pursuant to Rule 14a-8(i)(7) as relating to the Company's ordinary business operations.

**B. The Proposal May be Excluded Pursuant to Rule 14a-8(i)(10) Because the Company Has Substantially Implemented the Proposal.**

Rule 14a-8(i)(10) permits a company to exclude a stockholder proposal if "the company has already substantially implemented the proposal." The Commission adopted the "substantially implemented" standard in 1983 after determining that the "previous formalistic application" of the rule defeated its purpose, which is to "avoid the possibility of shareholders having to consider matters which already have been favorably acted upon by the management." *See* the 1983 Release and Exchange Act Release No. 34-12598 (July 7, 1976). Accordingly, the actions requested by a proposal need not be "fully effected" provided that they have been "substantially implemented" by the company. *See* 1983 Release. Furthermore, the Staff has stated that "a determination that the company has substantially implemented the proposal depends upon whether its particular policies, practices and procedures compare favorably with the guidelines of the proposal." *Texaco, Inc.* (Mar. 6, 1991, *recon. granted* Mar. 28, 1991).

Applying this standard, the Staff has consistently permitted the exclusion of proposals under Rule 14a-8(i)(10) when it has determined that the company's policies, practices and procedures or public disclosures compare favorably with the guidelines of the proposal. *See, e.g.*,

*Wal-Mart Stores, Inc.* (Mar. 27, 2014); *Peabody Energy Corp.* (Feb. 25, 2014); *The Goldman Sachs Group, Inc.* (Feb. 12, 2014); *Hewlett-Packard Co.* (Dec. 18, 2013); *Deere & Co.* (Nov. 13, 2012); *Duke Energy Corp.* (Feb. 21, 2012); *Exelon Corp.* (Feb. 26, 2010); *ConAgra Foods, Inc.* (July 3, 2006); *The Gap, Inc.* (Mar. 16, 2001); *Nordstrom, Inc.* (Feb. 8, 1995); *Texaco, Inc.* (Mar. 6, 1991, *recon. granted* Mar. 28, 1991). In addition, the Staff has permitted exclusion under Rule 14a-8(i)(10) where a company already addressed the underlying concerns and satisfied the essential objectives of the proposal, even if the proposal had not been implemented exactly as proposed by the proponent. For example, in *PG&E Corp.* (Mar. 10, 2010), the Staff permitted exclusion under Rule 14a-8(i)(10) of a proposal requesting that the company provide a report disclosing, among other things, the company's standards for choosing the organizations to which the company makes charitable contributions and the "business rationale and purpose for each of the charitable contributions." In arguing that the proposal had been substantially implemented, the company referred to a website where the company had described its policies and guidelines for determining the types of grants that it makes and the types of requests that the company typically does not fund. Although the proposal appeared to contemplate disclosure of each and every charitable contribution, the Staff concluded that the company had substantially implemented the proposal. *See also, e.g., MGM Resorts Int'l* (Feb. 28, 2012) (permitting exclusion on substantial implementation grounds of a proposal requesting a report on the company's sustainability policies and performance, including multiple, objective statistical indicators, where the company published an annual sustainability report); *Exelon Corp.* (Feb. 26, 2010) (permitting exclusion on substantial implementation grounds of a proposal requesting a report disclosing policies and procedures for political contributions and monetary and non-monetary political contributions where the company had adopted corporate political contributions guidelines); *The Gap Inc.* (Mar. 16, 2001) (permitting exclusion on substantial implementation grounds of a proposal requesting a report on child labor practices of the company's suppliers where the company had established a code of vendor conduct, monitored compliance with the code, published information on its website about the code and monitoring programs and discussed child labor issues with stockholders).

As requested in the Proposal, the Company already provides disclosure regarding the criteria used for price increases of the Company's products, and such disclosure is available on the Company's publicly accessible website located at www.amgen.com. Specifically, under the "Responsibility" section of the website, the Company provides information that addresses "Access to Medicine," including "Reimbursement Support Services and Financial Assistance Programs," "Access to Investigational Medicines" and "The Value of Our Medicines." (*See* http://amgen.com/responsibility/access-to-medicine/). Screenshots of the information available on the Company's website are attached hereto as Exhibit B.

As a science-led company, the Company is committed to developing and delivering high quality, targeted medicines that make a difference to patients' lives and address some of society's most devastating and grievous illnesses. The Company believes that the price of a medicine should reflect the holistic economic value delivered to patients, providers and payers, the unmet medical need and the size of the patient population and be aligned with the investment and risk the Company undertakes to develop medicines and fund future scientific innovation. The Company's website identifies the core set of principles for responsible pricing across the world and notes that pricing policies for the Company's products take into account a number of important factors,

including, but not limited to: cost-effectiveness thresholds; budget impact in countries offering National Healthcare/Socialized Medicine; patient ability to pay; per-capital gross domestic product ("GDP"); and healthcare spending as a proportion of GDP. Additionally, the Company offers a number of reimbursement support services and financial assistance programs. As evidenced by the language of the Proposal, the Proposal's essential objective is to obtain disclosure on the criteria used for price increases of the Company's products. As discussed above, the Company provides significant disclosure on its website regarding its pricing policies and the specific factors it takes into consideration in determining the price of a product. Accordingly, although the Company's website does not provide specific disclosure of the amounts of price increases of certain products, the disclosure provided satisfies the essential objective of the Proposal.

The Proposal also requests that the Company provide "an assessment of the legislative, regulatory, reputation and financial risks" such price increases represent for the Company. Much of this disclosure is provided in the Company's annual report on Form 10-K for the year ended December 31, 2015 (the "Annual Report") and subsequent quarterly reports on Form 10-Q for the quarterly periods ended March 31 and September 30, 2016, respectively (the "Quarterly Reports"). For instance, the Annual Report explains that the Company's competitive positions may be impacted by price and reimbursement, among other factors, and identifies the risks that the Company could face as a result of increased public scrutiny of the price of drugs, heightened control over product pricing and patient access by government and private payers and/or changes to U.S. federal reimbursement policy resulting from legislative or regulatory action. The Quarterly Reports expand that discussion and address potential consequences of specific federal and state pricing and reimbursement policy actions that could impact the Company. *See* "Risk Factors—Our sales depend on coverage and reimbursement from third-party payers, and pricing and reimbursement pressures may affect our profitability" in the Annual Report and Quarterly Reports.

Further disclosure, as requested by the Proposal, regarding "the rationale and criteria used for these price increases, and an assessment of the legislative, regulatory, reputational and financial risks they represent" would result in disclosure of the Company's proprietary information. As indicated in the Proposal, such proprietary information may be excluded from the requested report. Given the current publicly available disclosures made by the Company on its website and in its Annual Report regarding the rationale and criteria for, and risks related to, price increases, the Company believes that it has substantially implemented the Proposal by addressing both its underlying concerns and its essential objective. Accordingly, the Company believes that it may properly exclude the Proposal from the 2017 Proxy Materials under Rule 14a-8(i)(10) as having been substantially implemented.

## III. CONCLUSION

Based upon the foregoing analysis, the Company hereby respectfully requests that the Staff confirm that it will not recommend enforcement action if the Proposal is excluded from the Company's 2017 Proxy Materials (i) pursuant to Rule 14a-8(i)(7) because it deals with a matter relating to the Company's ordinary business operations and (ii) pursuant to Rule 14a-8(i)(10) because the Company has already substantially implemented the Proposal.

* * * *

We would be pleased to provide any additional information and answer any questions that the Staff may have regarding this submission. If the Staff does not concur with the Company's position, we would appreciate an opportunity to confer with the Staff concerning this matter prior to the determination of the Staff's final position. In addition, the Company requests that the Proponents copy the undersigned on any response it may choose to make to the Staff, pursuant to Rule 14a-8(k).

If we can be of any further assistance in this matter, please do not hesitate to contact me at (805) 447-4734 or by electronic mail at robinson@amgen.com. Please acknowledge receipt of this letter by return electronic mail. Thank you for your attention to this matter.

Sincerely,

Andrea A. Robinson
Assistant Secretary and Associate General Counsel

cc: Donna Meyer, PhD
Mercy Investment Services

Catherine M. Rowan
Trinity Health

Ann Roberts
Dana Investment Advisors, Inc.

Susan Vickers, RSM
Dignity Health

W. Esther Ng
Congregation of the Sisters of Charity of the Incarnate Word, San Antonio

Rose Marie Stallbaumer, OSB
Benedictine Sisters of Mount St. Scholastica

Rose Marie Stallbaumer, OSB
Benedictine Sisters of Monasterio Pan de Vida

Judith Sinnwell, OSF
Sisters of St. Francis Charitable Trust

# Exhibit A

October 17, 2016
Jonathan P. Graham
Secretary
Amgen
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Mr. Graham:

Mercy Investment Services, Inc. (Mercy) is the investment program of the Sisters of Mercy of the Americas has long been concerned not only with the financial returns of its investments, but also with the social and ethical implications of its investments. We believe that a demonstrated corporate responsibility in matters of the environment, social and governance (ESG) concerns fosters long-term business success. Mercy Investment Services, Inc., a long-term investor, is currently the beneficial owner of shares of Amgen.

Mercy is submitting a shareholder resolution requesting that the Board of Directors issue a report by November 1, 2017, at reasonable expense and excluding proprietary information, listing the rates of price increases year-to-year of our company's top ten selling branded prescription drugs between 2010 and 2016, including the rationale and criteria used for these price increases, and an assessment of the legislative, regulatory, reputational and financial risks they represent for our company.

Mercy Investment Services, Inc. is filing the proposal for inclusion in the 2017 proxy statement, in accordance with Rule 14a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934. Mercy Investment Services, Inc. has been a shareholder continuously for more than one year holding at least $2000 in market value and will continue to invest in at least the requisite number of shares for proxy resolutions through the annual shareholders' meeting. A representative of the filers will attend the Annual Meeting to move the resolution as required by SEC rules. The verification of ownership is being sent to you separately by our custodian, a DTC participant. Mercy Investment Services, Inc. is serving as lead filer on this proposal.

We look forward to having productive conversations with the company. Please direct your responses to me via my contact information below. We would appreciate receiving a confirmation of receipt of this letter via the email address below.

Best regards,

Donna Meyer, PhD
Mercy Investment Services
2039 North Geyer Road
St. Louis, MO 63131
703-507-9651
dmeyer@mercyinvestments.org

**AMGEN**
**DISCLOSE CRITERIA USED FOR PRICE INCREASES ON TOP TEN DRUGS**

**RESOLVED:** Shareholders request the Board of Directors issue a report by November 1, 2017, at reasonable expense and excluding proprietary information, listing the rates of price increases year-to-year of our company's top ten selling branded prescription drugs between 2010 and 2016, including the rationale and criteria used for these price increases, and an assessment of the legislative, regulatory, reputational and financial risks they represent for our company.

**WHEREAS:**
IMS Health research cites Americans paid $310 billion (after taxes and rebates) for drugs in 2015, an 8.5% increase over 2014; while the Cost of Living Adjustment and the Consumer Price Index were both relatively flat at roughly 1.7% for this same period.

A Bloomberg/SSR Health analysis shows that the U.S. outpaces the world in the cost of branded medications in many cases by a factor of two, while a McKinsey report states prescription drugs in the U.S. cost 50% more than equivalent products in OECD countries.

A Kaiser Family Foundation poll found one in four people in the U.S. report difficulty affording their prescription medicines and 43% of people in fair or poor health did not fill a prescription, or said they cut pills in half or skipped doses because of cost. Risks of patient non-compliance due to the cost of medicines present a grave threat to public health and, in turn, to the economy.

According to a survey by the National Business Group on Health, "Overall, 80% of employers placed specialty pharmacy as one of the top three highest cost drivers."

Proposed legislation requiring pharmaceutical companies to justify price increases over 10% by disclosing what they spend on research, marketing and manufacturing was introduced in 12 states last year. California's Proposition 61 would prohibit states from paying more for prescription drugs than the lowest prices negotiated by the U.S. Department of Veterans Affairs. Given the public outcry over unsustainable drug costs, it is safe to assume further regulation on drug pricing is forthcoming.

According to the Campaign for Sustainable Rx Pricing, insurers, retailers, hospitals and medical professionals are all increasingly seeking proof of value for high-cost new drug treatments, and justification for increases for branded drugs already on the market.

Drug companies have become a lightning rod for criticism. According to a Kaiser study, 74% of Americans said big pharma is too concerned about making money and not concerned enough about helping people. In an NPR Marketplace interview, GlaxoSmithKline CEO Andrew Witty conceded: "There's no transparency around what the real price of everything is."

**SUPPORTING STATEMENT**
Current price increases severely limit access to life-saving medicines, particularly for economically challenged patients: this has serious repercussions for public health and the economy. Given our stated commitment to promoting public health and to mitigating risks, it is incumbent on our company to provide detailed justification for price increases.

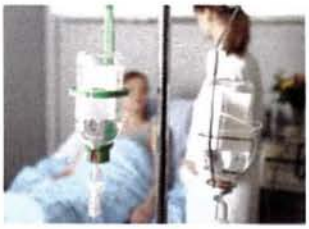
# Exhibit B

# ACCESS TO MEDICINE



Amgen's medicines make a difference for those facing serious illnesses and we believe patients should have access to them regardless of their ability to pay. We may also make our investigational medicines available, if appropriate.

Reimbursement Support Services and Financial Assistance Programs



Access to Investigational Medicines

The Value of Our Medicines

RESPONSIBILITY

Overview

Amgen Foundation

Access to Medicine

Reimbursement Support Services and Financial Assistance Programs

Access to Investigational Medicines

The Value of Our Medicines

2015 Environmental Sustainability Report

Supplier Sustainability

Grants and Giving

Safety and Wellness

# ACCESS TO MEDICINE



## Reimbursement Support Services and Financial Assistance Programs

Click on the relevant Amgen product below to obtain information regarding coverage, reimbursement support services, patient resources and financial assistance programs.

Aranesp (darbepoetin alfa)

BLINCYTO (blinatumomab)

Corlanor (ivabradine)

Enbrel etanercept

EPOGEN (EPOETIN ALFA)

IMLYGIC

Kyprolis

Neulasta (pegfilgrastim)

NEUPOGEN (FILGRASTIM)

Nplate romiplostim

prolia (denosumab)

Repatha (evolocumab)

Sensipar (cinacalcet) Tablets 30mg 60mg 90mg

Vectibix (panitumumab)

XGEVA (denosumab)

RESPONSIBILITY

Overview

Amgen Foundation

Access to Medicine

Reimbursement Support Services and Financial Assistance Programs

Access to Investigational Medicines

The Value of Our Medicines

2015 Environmental Sustainability Report

Supplier Sustainability

Grants and Giving

Safety and Wellness

Related Links

Privacy Pledge to Patients

# For Patients With No or Limited Drug Coverage

Amgen is committed to assisting patients with no or limited drug coverage access the medicines they need.

Through Amgen's charitable patient assistance program, Amgen Safety Net Foundation, Amgen supports qualifying patients in the United States who might go without important medicines because of financial barriers. This program provides medicines to patients experiencing financial difficulty at no cost.

## AMGEN Safety Net Foundation
### Serving Patients in Need™

Amgen Safety Net Foundation supports financially needy uninsured patients and certain underinsured patients who do not have coverage for particular Amgen medications. Products supported by Amgen Safety Net Foundation include Aranesp® (darbepoetin alfa), BLINCYTO® (blinatumomab), Corlanor® (ivabradine), Enbrel® (etanercept), EPOGEN® (epoetin alfa) for dialysis use only, IMLYGIC® (talimogene laherparepvec), Kyprolis® (carfilzomib), Neulasta® (pegfilgrastim), NEUPOGEN® (filgrastim), Nplate® (romiplostim), Prolia® (denosumab), Repatha® (evolocumab), Sensipar® (cinacalcet), Vectibix® (panitumumab), and XGEVA® (denosumab). For more information, visit www.amgensafetynetfoundation.com.

*This information is intended for residents of the U.S. only.*

# Access to Investigational Medicines

To serve patients, Amgen engages in clinical research with the goal of obtaining regulatory approval of its products.

Clinical trials allow Amgen to evaluate investigational new treatments in volunteers in order to generate the safety and efficacy information needed to obtain approval of those treatments and make them available to the broader patient population. Outside of a clinical trial, access to Amgen's investigational products would be considered under limited circumstances only, and as permitted by applicable law, in the following situations.

- Amgen may provide **continued access** to its investigational products to **research participants** once a clinical trial is complete.
- Amgen may provide physician-requested **expanded access** to its investigational products to patients with serious or immediately life-threatening diseases who lack other therapeutic options, cannot join an active clinical trial of the investigational product, and where the potential benefits of the investigational product are greater than the known risks in the disease indication (as described by the criteria below).

**Criteria Used for Considering Requests for Expanded Access**

- The patient has a serious or immediately life threatening disease or condition.
- There is no comparable or satisfactory alternative therapy for the disease or condition.
- Sufficient clinical evidence of safety and effectiveness in the indication has been established, the potential benefit justifies the potential risks, and the potential risks are not unreasonable within the context of the disease or condition.
- Product is under active development in the indication and expanded access will not interfere with the development of the product.
- Amgen has adequate supply of investigational product.
- There is a regulatory mechanism in the country or region to support expanded access.

**Process for Requesting Expanded Access**

A treating physician may request information about how to apply for access to one of Amgen's investigational products by contacting Amgen Medical Information at medinfo@amgen.com. All physicians who receive Amgen investigational product through expanded access are required to comply with all applicable laws and regulations, and contractual conditions, including those relating to safety reporting.

RESPONSIBILITY

Overview
Amgen Foundation
Access to Medicine
Reimbursement Support Services and Financial Assistance Programs
Access to Investigational Medicines
The Value of Our Medicines
2015 Environmental Sustainability Report
Supplier Sustainability
Grants and Giving
Safety and Wellness

# Drug Costs in Perspective

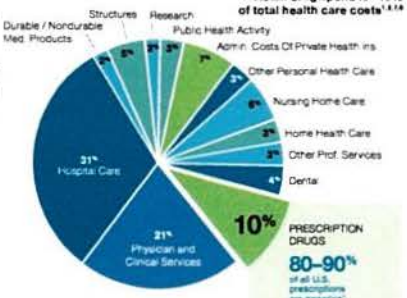
Are prescription drug prices really the primary drivers of rising health care costs and the cause of patient financial burden? Here we shed light on the key components of health care and their contribution to rising costs, the disproportionate 'skin in the game' for patients with regard to prescription medicines and ask what can we do to ensure that health care remains affordable for all.

## Patients contribute more for prescription medicines even though medicines represent only 10% of total health care spend.[1]

Spending on retail prescription medicines is ~10% of total U.S. health care spending, has grown in line with other health care prices and is predicted to remain around 10% until 2023.[2] Even with the inclusion of non-retail specialty medicines, prescription drug spend is only 13% of total spending.[3] Conversely, hospital and physician services consume ~50% of every $1 and have grown ~70% since 2004.[1,4] Despite this, a patient contributes 4x more for medicines compared to hospital care.[5]

**Insurers require patients to contribute 4x more for medicines than hospital care[5]**


**Retail drug spend is ~10% of total health care costs[1,4,14]**




## What's causing my 'financial burden'?

If you feel like you pay more for health care that's because you do! Insurers have increased your premiums; introduced more cost-sharing tiers and co-pay tiers for branded therapies and increasingly shifted to co-insurance benefit designs where patients contribute as much as 40% of all pharmacy costs.[7]

**Family health care premiums have almost doubled[8]**


**Plans increasingly charge patients a percentage of a medicine's total cost rather than fixed copays[9]**


**The sickest 3–4%patients pay 15x more out of pocket costs than the national average for specialty medicines[10]**


## Practices that increase the financial burden have negative impacts on patients and health care systems.

**DOUBLING MEDICATION COPAYS FOR CHRONIC CONDITIONS...[11]**


## Avoiding the medical and pharmacy expenses that result from non-adherence to medicines would cover the annual prescription drug bill.[7,11]


## A dynamic and competitive market creates headroom to fund innovation.

Marketplace competition drives rebates typically in the 20-40% range.[12] Consequently, the published **list price is significantly different to the net price** received by the manufacturer. Unlike any other aspect of health care, medicine prices tend to **decrease** at patent expiration, by as much as **90%** within months - creating additional funding available for innovation and ensure that U.S. patients benefit first from the latest scientific advances.[13]

**SIGNIFICANT PRICE CONCESSIONS ARE COMMON IN TODAY'S COMPETITIVE MARKET PLACE**

**23.1%**[4,14] Medicaid
*Mandatory rebates that can be negotiated further
**Average minimum discount

**22.5%**[**4,14] 340B Hospitals

**36%**[4,13] Insurance Plans and Pharmacy Benefit Managers

### In 2012...

Savings created by patent expirations of branded products were more than enough to pay for desperately needed, innovative medicines.

**$29B** Savings due to patent expiries could have paid the total oncology drugs bill[15]

### ...and the innovation system is working

**$91 Billion**
Saved on small molecule patent expiries over the past 5 years[16]

**$84 Billion**
Net savings estimated for the next 5 years for small molecules[16]

### How we price our medicines...

- Are based on value brought to patients, providers, payers and society
- Align with population size, investment and risk we undertake
- Fund continued scientific innovation and ensure access to our therapies
- Balance affordability with availability of patient assistance programs

AMGEN

### Our Solution

At Amgen, we believe providers and patients need choices to effectively manage complicated diseases. We are committed to an ongoing dialogue with patients, providers, payers, policymakers and regulators to find ways to promote innovation and value-based solutions to alleviate the financial and societal burden of some of the world's most serious diseases.


1. Keehan SP et al. National Health Expenditure Projections, 2014-2024 Health Expenditures. CMS. July 2015. Health Affairs. 2. California Biotechnology Foundation. Breakthrough Medications Save Money and Save Lives. February 2015.[15]. 3. Drug Channels Institute. Share of U.S. National Health Expenditures, by Major Spending Category, 1973-2023. September 2014. 4. Center for Sustainable Health Spending. Care Brief. 5. Net Price Out of the Prescription Drug Share of National Health Expenditures, including Nonretail. October 2014. 6. PhRMA. Biopharmaceuticals in Perspective. ChartPack. Version 5.0. Spring 2015. Washington DC. 8. PhRMA. National health expenditures by type of service and source of funds. CY 1960-2013. Baltimore, Md. CMS. 2013. 7. IMS Institute for Healthcare Informatics. Medicines Use and Spending Shifts. A Review of the Use of Medicines in the U.S. in 2013. April 2014. 8. Fleming C. Specialty Drugs: Cost, Impact, and Value. Health Affairs Blog. October 2014. 9. Kaiser Family Foundation/Health Research & Educational Trust. Employer Health Benefits. 2014 Annual survey. 10. Goldman DP. Pharmacy Benefits and the Use of Drugs by the Chronically Ill. JAMA. 2004 May 19;291(19):2344-50. 11. Express Scripts, Inc. 2013 Drug Trend Report. Annual Report. April 2014. 12. Baker J et al. Rising US Rebates limit margin expansion. Credit Suisse Annual Report. May 2015. 13. Amgen Inc. Data on file. IMS Consulting Group. Measuring Impact of LOE. May 2015. 14. Medicare Payment Advisory Commission. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015. Washington, DC. 15. IMS Institute for Healthcare Informatics. Declining medicines Use and Costs: Not Better or Worse. May 2013. 16. IMS Institute. Medicines Use and Shifting Cost of Care. April 2014. 17. Kaiser/HRET Survey of Employer Sponsored Health Benefits. 2000-2015.

# The Real Value of Innovative Medicine

In order to create a sustainable health care system, it's important for all stakeholders to holistically look at the burden and overall cost of disease—not just the cost of the critical interventions. If we don't account for the value of medicine, we're not looking at the full picture.

The challenge we face in addressing health care spending is that many stakeholders view the problem from a narrow silo or focus on the short-term financial or budget impact of paying for innovation.

## But it's critical that we address the real problem—the rising cost of disease.

### CARDIOVASCULAR DISEASE

CAUSES **1/3** DEATHS IN THE U.S.

In 2011, cardiovascular disease was estimated to cost the U.S. **$320 billion** and could be as high as **$686 billion,** based on projections for 2015[1]

**#1 KILLER** in the U.S. with **1 DEATH EVERY 40 SECONDS**[2]

### CANCER

**2nd** leading cause of death in the U.S.[2]

Kills over **500,000** Americans each year[2]

Every **1% reduction** in the long-term cancer-related death rate yields **$500 billion** for society[3]

### ALZHEIMER'S DISEASE

Impacts **5.3 MILLION** Americans[4]

Projected to cost more than **$450 BILLION** by 2030 & **$1.1 TRILLION** by 2050[5]

## HIV IN THE '80s

Consider the financial burden of HIV in the 1980s.

"AIDS Treatment Could Cost **$5 Billion a Year**[6]"
—New York Times, September 1987

"Experts estimate the AIDS dead will reach total annual costs of **$66.5 billion** by 1991—a figure that could bankrupt the health care system."
—Washington Post, June 1987

"... weeks ... months ..."

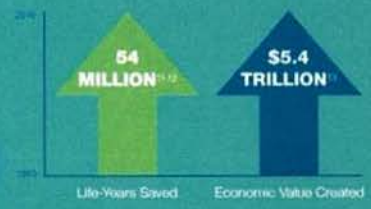
## AND HIV TODAY

HIV DEATH RATE **DOWN** **82%**[10]

Despite focus on the high cost of cancer treatments, we're making

## CRITICAL BREAKTHROUGHS IN CANCER

Innovators only captured 5%–9% of the **$1.9 trillion** of economic value generated through people living longer, healthier, more productive lives.[8]




5-yr Survival Rates Are Up Since Mid-1970s[14]


Approximately 80% of the increase in survival rates can be attributed to innovations in treatment[15]

AMGEN®

Innovation requires the power to explore and the time to stimulate change. Innovative biopharmaceuticals are part of the solution to the significant burden of cancer, cardiovascular and other serious diseases that impact patients and society.

### SO WHAT ARE *WE* DOING?

To address some of health care's most pressing challenges, Amgen uses insights from human genetics and biology to innovate biologics and decrease the cost and burden of disease. We are also actively working to:

- Evolve manufacturing to drive cost down through innovation
- Speed up and reduce the cost of bringing new innovative drugs to market
- Develop innovative new technologies to engage patients/providers to ensure optimal value is derived from our product
- Partner to improve overall population health
- Serve as a leading manufacturer of high-quality and reliably supplied biosimilars
- Understand the importance of precision medicine to ensure the right patients receive the right treatment, at the right time

**Precision medicine is important to ensure the right patients receive the right treatment, at the right time. At Amgen, we more than understand this. We believe in it.**

# The Price of Our Medicines

THE VALUE OF OUR MEDICINES

The Price of Our Medicines

Amgen's commitment to innovation has led us to launch groundbreaking therapies to treat serious illnesses. To ensure we meet the needs of patients who can benefit from our medicines worldwide, Amgen is committed to producing safe and effective therapies that can be appropriately accessed by the patients who need them most.

We follow a core set of principles for responsible pricing across the world, including developing countries, which include the following considerations:

- Reflects the economic value to society generated through improvement in life expectancy or reduction in risk of disease- or-treatment-related complications
- Reflects the clinical benefits and any medical costs avoided, and broader value to patients, caregivers and payers
- Enables access to medicines for appropriate patients
- Recognizes the local healthcare infrastructure and elements of the product supply chain as well as the competitive landscape of each country
- Enables continued investment to fund scientific innovation

In our efforts to balance local economic constraints and appropriate access to innovative therapies we may employ price policies that vary within regions and even within a given country. Price policies for Amgen products take into account a number of important factors in each country, including but not limited to:

- **Cost-effectiveness thresholds**
- **Budget impact in countries offering National Healthcare / Socialized Medicine**
- **Patient ability to pay**
- **Per-Capita Gross Domestic Product (GDP)**
- **Healthcare spending as a proportion of GDP**

While our product pricing aims to ensure patient access, in some countries adaptive pricing alone may not guarantee access to our medicines. Other elements and activities beyond Amgen's control such as healthcare infrastructure, supply chain / distribution structure, and public health funding priorities may impact access and affordability of Amgen products for patients who can benefit from our medicines.

# The Value of Our Medicines

As a science-led company, Amgen is committed to developing and delivering high quality, targeted medicines that make a difference to patients' lives and address some of society's most devastating and grievous illnesses.

Our objective as an organization is aligned with that of any healthcare system – to improve the health of the populations we serve, and to deliver healthcare solutions that help individuals lead longer, healthier and more productive lives. Our innovative medicines and healthcare solutions improve patient productivity and quality of life, while helping to reduce healthcare and societal costs, such as medical spending, hospital costs and physician office visit expenditures.

We believe that the price of a medicine should reflect the holistic economic value delivered to patients, providers and payers, the unmet medical need, the size of the patient population and be aligned with the investment and risk Amgen undertakes to develop medicines as well as fund future scientific innovation.

To create a sustainable healthcare system, all stakeholders must recognize that the overall economic burden of disease will make health care costs unsustainable, and that innovative medicines are part of the solution and not the problem. At Amgen, we are committed to an ongoing dialogue with patients, providers, payers, policymakers and regulators to find ways to promote innovation, while also alleviating the financial and societal burden of some of the world's most serious diseases.

We don't just believe that innovation is critical to the development of our medicines. Amgen also seeks to drive innovation in the way that our medicines are created, reimbursed and accessed by the patients who need them most. That's why we're working to:

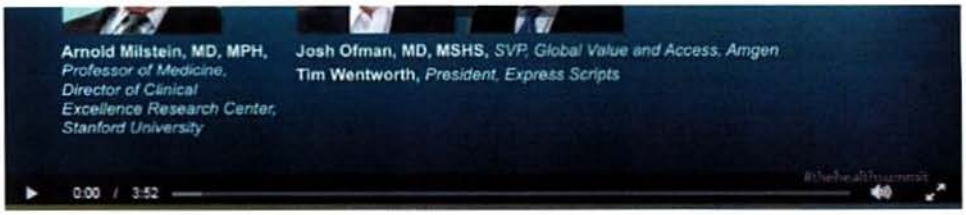
- Provide cost-effective solutions, including biosimilars, for patients around the globe
- Evolve manufacturing processes to drive down costs
- Develop advanced new technologies to engage patients and providers to ensure optimal value is derived from our products
- Foster partnerships with payers to improve overall population health to ensure we are delivering our medicines to the patients who need them most
- Accelerate discovery and development of new medicines through clinical trial efficiencies
- Continue to be a leading manufacturer of high-quality and reliably supplied medicines

## Joshua J. Ofman, MD, MSHS Senior Vice President, Global Value, Access and Policy at Amgen Talks About Value

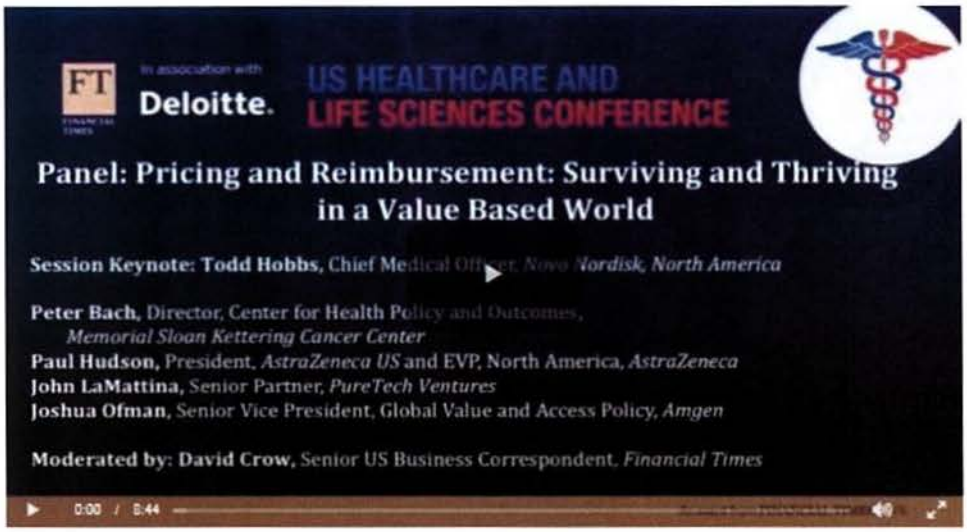
**Video: Health Evolution Summit Panel Discussion - "Building the Business Case for High-Priced Therapeutics"**


RESPONSIBILITY

Overview
Amgen Foundation
Access to Medicine
Reimbursement Support Services and Financial Assistance Programs
Access to Investigational Medicines
The Value of Our Medicines
The Price of Our Medicines
2015 Environmental Sustainability Report
Supplier Sustainability
Grants and Giving
Safety and Wellness




**Video: Financial Times Panel Discussion - "Pricing and Reimbursement: Surviving and Thriving in a Value Based World"**




## The Price of Our Medicines

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**Infographic: The Real Value of Innovative Medicine**

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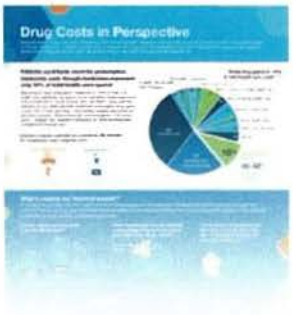
**Infographic: Drug Costs in Perspective**

Click Image to Expand

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