Greater Tompkins County Municipal Health Insurance Consortium

Audit and Finance Committee

July 26, 2016 - **3:30 p.m.**

Old Jail Conference Room

1. Call to Order (3:30) — Thayer

2. Approve Minutes of June 28, 2016 Meeting (3:32)

3. Executive Director's Report (3:35) — Barber
   a. Update from Joint Committee on Plan Structure and Design
      RESOLUTION: Recommendation to the Board of Directors to establish target Actuarial Values for the Platinum, Gold, Silver, and Bronze Metal Level Benefit Plans
   b. Financial Audit RFP?
   c. Status of co-investing with BOCES to increase reserve fund interest rate
   d. DFS Audit for 2012-2015
   e. Update on Municipal Interest in Joining the Consortium
   f. Cayuga Heights and MCA Section A3

4. 2016 Financial Update (3:50) — Locey

5. 2017 Budget Development (4:00) — Locey
   a. Rx Claims trend model

6. PBM RFP Report (4:30) — Locey

7. Top 3 Highmark Suggestions for Managing Risks (4:35) — Locey

8. Continued Discussion of Strategies to address escalating Specialty drug costs (4:40) — Locey & Feeley

9. Next Agenda Items (4:55)

10. Adjourn (5:00)

Next Meeting: August 23, 2016

Audit and Finance Committee – DRAFT
June 28, 2016 – 3:30 p.m.
Old Jail Conference Room

Present: Mack Cook, Peter Salton, Rordan Hart, Chuck Rankin (arrived at 3:33 p.m.)
Guests: Don Barber, Steve Locey (via conference call), Judy Drake, Rick Snyder, Aldwin Bennett, Cortland County Common Council; Meghan Feeley, Kaleigh Rascoe, ProAct
Excused: Steve Thayer, Laura Shawley, Phil VanWormer

Call to Order

Mr. Cook called the meeting to order at 3:30 p.m.

Approval of Minutes of May 17, 2016

It was MOVED by Mr. Hart, seconded by Mr. Salton, and unanimously adopted by voice vote by members present, to approve the minutes of May 17, 2016 as corrected. MINUTES APPROVED.

Mr. Rankin arrived at this time.

Executive Director's Report

Joint Committee on Plan Structure and Design

Mr. Barber reported the Joint Committee is working on the actuarial values for the metal level plans and at the last meeting put together a trial proposal for members to take back to their bargaining units. The discussion included adjusting goals for the Platinum and Gold Plans down by 3%, the Silver Plan by 7%, and the Bronze Plan down by 5%. Because of what has been seen with the changes in the actuarial values for the Silver and Bronze Plans it is likely they will have to be adjusted again in the following year and that change would likely be sufficient for two years. The Committee will meet in a couple of weeks and has a number of options of areas that can be adjusted within each metal plan. At that meeting the Committee does not have to accept those but will adopt an actuarial goal for each of the plans. He noted that if the Consortium increases the premium rate by 5% overall, the Platinum Plan would only go up by 3%. Whenever the actuarial value is changed it means the member is paying more and the Consortium should see a subsequent reduction in claims activity.

Prescription Drug Manager Request for Proposals

Mr. Barber reported the Request for Proposals for Prescription Drug Manager was released on June 22nd and was done for the first time through the County's electronic system. He will be setting up a meeting time for the Committee to review responses and will bring a preliminary report back to the next meeting of this Committee.

Medical Claims Auditing Process

Mr. Barber said at the last meeting the Board meeting action was taken to move forward with BMI Audit Services for the 2014-2015 medical claims audit. He reviewed a draft service agreement that members were provided and said the structure of the document is the same as the previous agreement although the pricing is a little different. The document defines a standard sampling BMI will pull from and specific targets that were identified in the last audit that will be looked at. The cost is a fixed price of $46,575. The previous medical claims audit performed by BMI was $49,500. He said BMI is prepared to begin the audit.

It was MOVED by Mr. Rankin, seconded by Mr. Salton, and unanimously adopted by voice vote members present, to authorize the Chair of the Board of Directors to sign an agreement with BMI Audit Services for the purpose of executing a contract for medical claims auditing services. MOTION CARRIED.

Municipal Investments

Mr. Barber reported he met with the Executive Director for the BOCES Consortium about their efforts to increase their rate of return on reserves. They talked with a group that invests municipal funds (PFM); they are looking at a two to three year span for the investments they have. He explained each investment has a yield curve with an interest rate that is paid at periods of three months, six months, one year, two-year, three-year, five-year, ten-year, and thirty-year increments and the yield curve changes from time to time. PFM works with a book of business within that yield curve to get the best return possible. By trading within that yield curve the type of investments that New York State municipalities are allowed to invest in, which are principal secure, they are able to get rates of return that are currently at one percent or higher. This is about ten times higher than what municipalities are currently getting. He said they are hoping to have a webinar that members of this Committee will be asked to participate in.

Financial Audit

Mr. Barber said last Fall there was discussion of the Consortium doing an RFP for Inserno & Co. LLP (formerly CDLM), and a decision was made to continue with them for the 2015 audit which would be the firm's fifth year auditing the Consortium'a financial records. He asked for direction from the Committee on whether he should move forward with preparing an RFP for the 2016 audit. The Consortium has used this firm since the Consortium began and was going to do an RFP last year; however, due to changes in the County Finance Department it was recommended that this be delayed for a year. Mr. Salton spoke of the importance of having an open process and allowing others to bid on a service and also possible consequences to having the same company looking at the Consortium's financial records indefinitely. Following a brief discussion it was suggested and agreed upon to defer this to the next meeting to allow for input from Mr. Snyder and Mr. Locey.

Excellus Appeal

Mr. Barber said members should have received a letter from Excellus in response to a request to Excellus to refund the amount paid by the Consortium for a claims appeal that was granted. The letter states Excellus approves the Consortium's request and the funds will be included in next month's claim payments.

It was MOVED by Mr. Salton, seconded by Mr. Hart, and unanimously adopted by voice vote by members present, to authorize the Chair of the Board of Directors to sign an appeal settlement agreement for the above matter with Excellus. MOTION CARRIED.

NYS DFS Audit

Mr. Barber reported he was contacted by the Department of Financial Service last week and informed the State will be starting a second audit of the Consortium that will begin in August. The first audit has not been completed; there were several recommendations of which all but three have been resolved. Information was sent to the Department six months ago but to date the Consortium has not received a response.

Municipal Interest in the Consortium

Mr. Barber reported at this time there are six small municipalities in Cortland and Cayuga Counties with an average of six contracts per municipality that have expressed interest in joining the Consortium. He will have more information for members at the next meeting.

Financial Report

Mr. Locey reviewed the Consortium's financial results for the first five months of 2016 and noted there has been some hyperinflation of claims. He is looking into the cause of the escalation and said they are seeing it in the medical side but it is predominantly in the prescription drug side. He reviewed budgeted versus actual results and stated the Consortium is close to budget on revenue. Medical claims are 3.23% ($333,000) above budget and prescription drug claims are 16.80% ($638,000). He noted for three of the last five months the Consortium has received $3.5 million in claim payments; in the 14 months prior to that there was only one month that exceeded $2.75 million. This is something they will keep an eye on as it is an area of concern. Mr. Locey said an adjustment was made to the Coordination fees that will be seen in future reports.

Mr. Locey called attention to drug expenses over the last three months being well above budget and said he is trying to identify the cause and has made requests for data from Excellus and ProAct. He reviewed budget performance data since the Consortium began and said the hyperinflation in drug expenses began in 2015 although it was offset by medical claims being so far below budget. Also included in the information provided to the Committee was trend data from the beginning of the Consortium and said the current medical claims trend is slightly over 9% on an average basis and 8.4% on drug claims.

He spoke of the Consortium moving forward and conversations he has had with Mr. Barber concerning adding more small municipalities in Cayuga and Cortland County. He said one thing that needs to be considered is at what point should pressure be placed on the larger entities to join, specifically counties in those areas, to help further stabilize the Consortium. When larger entities are added they bring a much larger demographic mix which reduces the risk of having an adverse risk selection. If a small employer with a very small population has a member with extraordinarily high claims the cost would be absorbed by the rest of the Consortium. He suggested having a conversation as the Consortium moves forward about limiting the number of small municipalities from a county that can become a participant if the county isn't in the Consortium.

Mr. Salton referred to the financial data presented and suggested getting a list of all of the diagnosis codes to see what they have been from year-to-year. Mr. Locey said he would like to wait for a couple of months to see if claims begin to trend back downward but if they don't this is something that can be looked into further.

Mr. Cook said Cortland County has not indicated any intent to join the Consortium and asked if that should be addressed before bringing in additional municipalities from that County. Mr. Barber said that because the Consortium is community-rated it is not known whether one municipality is paying more than another. To make this assessment it would require analyzing more data than is currently available. Another thing to consider is how the Consortium would be managed if a couple of large counties were brought in.

Mr. Locey reported on the preliminary 2017 budget and said it is built with a 5% premium increase; he used data from the first five months of 2016 and conservatively trended it forward. He said last year he used an aggregate trend for both medical and prescription drug but due to the hyperinflation being seen on the drug side trending has been done independently for each.

Ms. Feeley provided information on specialty medications which is the biggest driver in claims costs. She said ProAct is seeing about a 20% increase in utilization for all of its clients. She said they can run sample reports for the population if a fourth tier was brought in to see if

that would provide savings for the Consortium. She also brought information on a Premium Prescription Drug List which is an enhanced savings strategy that leverages exclusion capabilities with manufacturers to reduce costs, maintain affordable medication access, and promote use of lower-cost alternatives to members.

Mr. Barber asked if Ms. Feeley could run trend information to show what the increase in specialty drug usage is for the Consortium or a similar book of business. Ms. Feeley said she could take claims data and show what the savings would have been under different co-pay scenarios to show what the savings would have been. Mr. Cook said as the cost and usage of specialty drugs rise he would like to know if there has been a decrease on the medical side . He said it should be there but he has not been able to find it. Mr. Locey said this has been a long-standing issue in the health insurance industry. From the time the new specialty drugs became available the argument has been that although more is being spent on drugs there would be less spent on medical costs. That has not been the case because medical costs have continued to rise.

Mr. Cook asked if this is the time to begin talking about plan design. Mr. Locey said in the last two years there have been approximately 80 members who have received specialty drugs and there were only 800 prescriptions filled. The cost last year was $2.4 million. Mr. Locey said even if a $1,000 co-pay was put on that drug it would result in a savings of $785,000 and if a $100 co-pay were on the drug it would result in a savings of $78,000 out of $2.4 million. He said there can be discussion but it is difficult when this small of a population is driving this kind of cost.

Ms. Feeley said ProAct has a team of members who look for co-pay assistance programs for members and provided information on what drugs have co-pay assistance programs available. She will run a report and see what savings could be generated for the Consortium if this were implemented. Mr. Locey noted that everything under discussion involves collective bargaining. Mr. Cook said under the current system it would take four years or longer to bring a plan design into fruition and with the Consortium currently being 16-17% over-budget with prescription drug expenses it may be time to start looking at this. He also questioned how long co-pay assistance programs will be available. Ms. Feeley pharmaceutical companies have funds set aside for these programs to help people be able to receive their medication and although there is no assurance they will continue to exist she doesn't expect them to go away. Mr. Salton said a budget cannot be built around a program that may go away. He also spoke of the need for municipal board members to become educated about this.

Mr. Cook said the Consortium has to have products and a portfolio that its covered lives can obtain regardless of who pays for it. He said holding to a two and three-tier drug plan over the long-term may place the Consortium at a disadvantage of having an affordable portfolio of plans. Ms. Feeley said last year the Plan cost for Tier I drugs in the Plan was $30.27 per script; Tier II - $336; Tier III - $283; and Specialty Drugs - $3,057. Mr. Locey suggested looking at the copay structure going forward to make is more reflective of the actual pricing. In addition, the Consortium can continue to look at the areas that were presented by Highmark that have a potential for savings.

HighMark Suggestions for Managing Risk

Mr. Locey said he reviewed the suggestions made by HighMark at the last meeting and some of the suggestions have been implemented. An area of concern is the Ithaca Dialysis clinic being out-of-network and said that is something that Excellus needs to continue to work on. Locey and Cahill will continue to go through the list from HighMark and develop some

strategies that can be developed to help address costs. Mr. Salton asked if the Consortium can look at more data that could help to make more cost-effective. Mr. Locey said more data can be provided but the Consortium should know what the goal is in having the data and what it is looking to accomplish. Mr. Barber said there are firms that can look at data and do an analysis but at this time the Consortium is community-rated and needs to look at data from a global perspective. The Consortium currently receives utilization data from Excellus and ProAct but if there is additional data that is desired there needs to be a decision made as how that data will be viewed and used.

Mr. Barber asked Mr. Locey to review the suggestions and develop a list of three priorities that the Consortium can work on.

Next Meeting Agenda Items

The following items were suggested for inclusion in the June meeting agenda:

- Continue discussion on addressing escalating prescription drug costs (review population on each prescription drug plan, options for copays and specialty drugs);
- Review list of suggestions from HighMark for potential cost savings;
- Discussion of preliminary 2017 budget;
- Contract for auditing of Consortium's financial records;
- Prescription Drug Manager RFP

Adjournment

The meeting adjourned at 5:03 p.m.

RESOLUTION NO. - RECOMMENDATION BY THE AUDIT AND FINANCE COMMITTEE ON PLAN STRUCTURE AND DESIGN TO THE GTCMHIC BOARD OF DIRECTORS ON BENEFIT PLAN CHANGES TO MAINTAIN ACTUARIAL VALUES OF METAL LEVEL PLANS

WHEREAS, the Greater Tompkins County Municipal Health Insurance Consortium (GTCMHIC) Board of Directors pursuant to Resolutions No. 016-2014 and No. 014-2015 adopted the GTCMHIC Standard Platinum, Gold, Silver, and Bronze Plans adding said plans to the available benefit plan menu, and

WHEREAS, the GTCMHIC standard metal level plans, Platinum, Gold, Silver, and Bronze, are designed to maintain an actuarial value (AV) of 90%, 80%, 70% and 60%, respectively on an annual basis within an acceptable deviation of + or – 2%, and

WHEREAS, each year, the AV is calculated by the Consortium's medical plan administrator and/or plan consultant using the AV Calculator developed by the Centers for Medicare & Medicaid Services (CMS) Center for Consumer Information & Insurance Oversight (CCIIO) which was implemented in accordance with the Patient Protection and Affordable Care Act (ACA). If, in any given year, such calculator is no longer available or in use, the Consortium will have an independent Actuary develop the AV of these health insurance plans. In either case, it is the intent that the result of the AV calculation will represent an empirical estimate of the AV calculated in a manner that provides a close approximation to the actual average spending by a wide range of consumers in a standard population, and

WHEREAS, the GTCMHIC Joint Committee on Plan Structure and Design, at the July 7, 2016 meeting, adopted a resolution to provide the Audit and Finance Committee with recommended plan design changes necessary to maintain the target AV of the GTCMHIC Standard Platinum, Gold, Silver, and Bronze Plans for the 2017 Plan Year, and now therefore be it

RESOLVED, That the Audit and Finance Committee on Benefit Plan Design recommends to the GTCMHIC Board of Directors to establish target Actuarial Values for the Platinum, Gold, Silver, and Bronze Benefit Plans of 91.3%, 79.47%, 70.69% and 61.25% respectively.

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WHEREAS, the GTCMHIC Joint Committee on Plan Structure and Design, at the July 7, 2016 meeting, has the opportunity to provide the Audit and Finance Committee with recommended plan design changes necessary to maintain the target AV of the GTCMHIC Standard Platinum, Gold, Silver, and Bronze Plans for the 2017 Plan Year, and

WHEREAS, the Joint Committee on Plan Structure and Design has received information and benefit options for plan changes to attain the necessary Actuarial Value (AV) and the Committee is in an informed position to recommend benefit changes for each metal level plan necessary to maintain each plan's AV for the 2017 Plan Year, now therefore be it

RESOLVED, That the Joint Committee on Benefit Plan Design recommends to the GTCMHIC Board of Directors to establish target Actuarial Values for the Platinum, Gold, Silver, and Bronze Benefit Plans of 91.3%, 79.47%, 70.69% and 61.25% respectively.

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Greater Tompkins County Municipal Health Insurance Consortium

2016 Standard Metal Level Plans and 2017 Recommended Plan Options

Benefit Description		2016 Platinum Plan	2017 Recommended	2016 Gold Plan	2017 Recommended	2016 Silver Plan	2017 Recommended	2016 Bronze Plan	2017 Recommended
Actuarial Value		92.60%	91.13%	84.17%	79.47%	79.23%	70.69%	67.92%	61.23%
In-Network Deductible	**Individual**	$0.00	$0.00	$500.00	$1,300.00	$1,300.00	$1,800.00	$3,500.00	$6,550.00
	Family	$0.00	$0.00	$1,500.00	$2,600.00	$2,600.00	$3,600.00	$7,000.00	$13,100.00
Deductible Aggregation		Individual	Individual	Individual	Family Aggregate	Family	Family	Individual	Family
Out-of-Network Deductible	**Individual**	$500.00	$500.00	Included w/ In-Network	$2,600.00	Included w/ In-Network	$3,600.00	Included w/ In-Network	$13,100.00
	Family	$1,500.00	$1,500.00		$5,200.00		$7,200.00		$26,200.00
Out-of-Pocket Maximum Aggregation		Individual	Individual	Individual	Family Aggregate	Family	Family	Individual	Family
In-Network Out-of-Pocket Maximum *Includes Rx Copayments*	**Individual**	$2,000.00	$2,000.00	$3,000.00	$3,000.00	$3,000.00	$6,000.00	$6,350.00	$6,550.00
	Family	$6,000.00	$6,000.00	$9,000.00	$6,000.00	$6,000.00	$12,000.00	$12,700.00	$13,100.00
Out-of-Network Out-of Pocket Maximum	**Individual**	$2,000.00	$4,000.00	Included w/ In-Network	$6,000.00	Included w/ In-Network	$12,000.00	Included w/ In-Network	$13,100.00
	Family	$6,000.00	$12,000.00		$12,000.00		$24,000.00		$26,200.00
Primary Care Physician Copay		$15.00	$15.00	$25.00	n/a	n/a	n/a	n/a	n/a
Specialist Copay		$25.00	$25.00	$40.00	n/a	n/a	n/a	n/a	n/a
Chiropractor Copay		$25.00	$25.00	$40.00	n/a	n/a	n/a	n/a	n/a
Diagnostic Lab Copay		$0.00	$25.00						
In-Network Coinsurance		0.00%	0.00%	20.00%	20.00%	20.00%	30.00%	20.00%	0.00%
Out-of-Network Coinsurance		20.00%	20.00%	40.00%	40.00%	40.00%	50.00%	40.00%	0.00%
Pharmacy Copayments Retail (30 Day Supply) *Not Subject to Deductible*	**Tier 1**	$10.00	$5.00	$5.00	$5.00	$5.00	$5.00	$5.00	$5.00
	Tier 2	$30.00	$35.00	$35.00	$35.00	$35.00	$35.00	$35.00	$35.00
	Tier 3	$50.00	$70.00	$70.00	$70.00	$70.00	$70.00	$70.00	$70.00
High Deductible Health Plan		No	No	No	Yes	Yes	Yes	Yes	Yes
Health Savings Account Eligible.		No	No	No	Yes	Yes	Yes	Yes	Yes
Premium Rates	**Individual**	**$556.97**	**$576.63**	**$500.89**	**$502.39**	**$415.67**	**$400.96**	**$324.72**	**$319.23**
	Family	**$1,448.13**	**$1,499.25**	**$1,302.30**	**$1,306.21**	**$1,080.74**	**$1,042.48**	**$844.26**	**$829.99**
	% Change	**n/a**	**3.53%**	**n/a**	**0.30%**	**n/a**	**-3.54%**	**n/a**	**-1.69%**

ConsumerReports

Is There a Cure for High Drug Prices?

The cost of prescription drugs for tens of millions of Americans rose $2 billion last year, and all signs point to a continued rise. At stake is nothing less than the ability of Americans to afford the medicines they need. Can we stop the madness?

By Consumer Reports

June 21, 2016

Last August, Martin Shkreli, then the CEO of Turing Pharmaceuticals, did something considered so reprehensible that he was dubbed "the most hated man in America." What caused the outrage? He increased the price of a little-known but important drug called Daraprim from $13.50 to $750 per pill. Daraprim is the best treatment for toxoplasmosis, an infection to which those with HIV/AIDs or cancer are susceptible.

The story went viral, and calls came from around the country, including from U.S. Rep. Elijah Cummings, D-Md., to stop drug entrepreneurs from gouging consumers for pure profit. Overnight, Shkreli became the poster child of pharmaceutical greed. And yet raising the price of a drug by that much is 100 percent legal.

What makes the case of Daraprim so important is that it brought a serious—and growing—healthcare problem out into the open: America spends a tremendous amount of money for prescription drugs—$424 billion last year alone before discounts, according to a new report by IMS Institute for Healthcare Informatics, a firm that tracks the pharmaceutical industry. And that number is rising fast with no sign of slowing down. What's more, there are few regulations that shield

consumers from the Martin Shkrelis of the world, or from drug companies that decide to raise prices to astronomical levels.

Martin Shkreli, former CEO of Turing Pharmaceuticals

The Rampant Rise of Drug Prices

The practice of raising drug prices on new—and old—medications is common and widespread. From a nationally representative telephone poll conducted by Consumer Reports Best Buy Drugs in March, we learned that three in 10 Americans (about 32 million people) were hit with price hikes within the previous 12 months, costing them an average of $63 more for a drug they routinely take—and a few paid $500 or more. We also found price increases on everything from longtime generics used to treat common conditions such as diabetes, high blood pressure, and high cholesterol to new treatments for diseases such as hepatitis C. Our poll shows that when people were hit with higher drug costs, they were more likely to take unhealthy measures such as skipping doctor appointments, tests, or procedures, or not filling their prescriptions or taking them as directed.

Take the case of Marlene Condon, a nature writer living in Crozet, Va. Two years ago she paid about $32 for 180 tablets of hydroxychloroquine (a generic available for almost two decades) to treat her rheumatoid arthritis. When the drug's price more than doubled to $75, Condon says she was annoyed but paid the bill

anyway. Then, last September, the price of her drug skyrocketed, costing her $500 out of pocket. Condon panicked and did what thousands of Americans do under those circumstances: She stopped taking the drug. Her arthritis pain grew much worse. Walking and doing simple household chores such as washing the dishes became almost impossible.

The Forces of Profit

Our analysis suggests that high prices for generic and brand-name drugs stem in part from a battle over profit between mammoth industries—big pharma and insurance companies—with consumers caught in the middle. On the one hand, pharmaceutical companies blame insurance companies for passing along high costs to consumers. And insurance companies point to very high-priced drugs for which there are few or no alternatives, which ultimately affects how much insurance coverage people receive and how much they must pay out of their pockets.

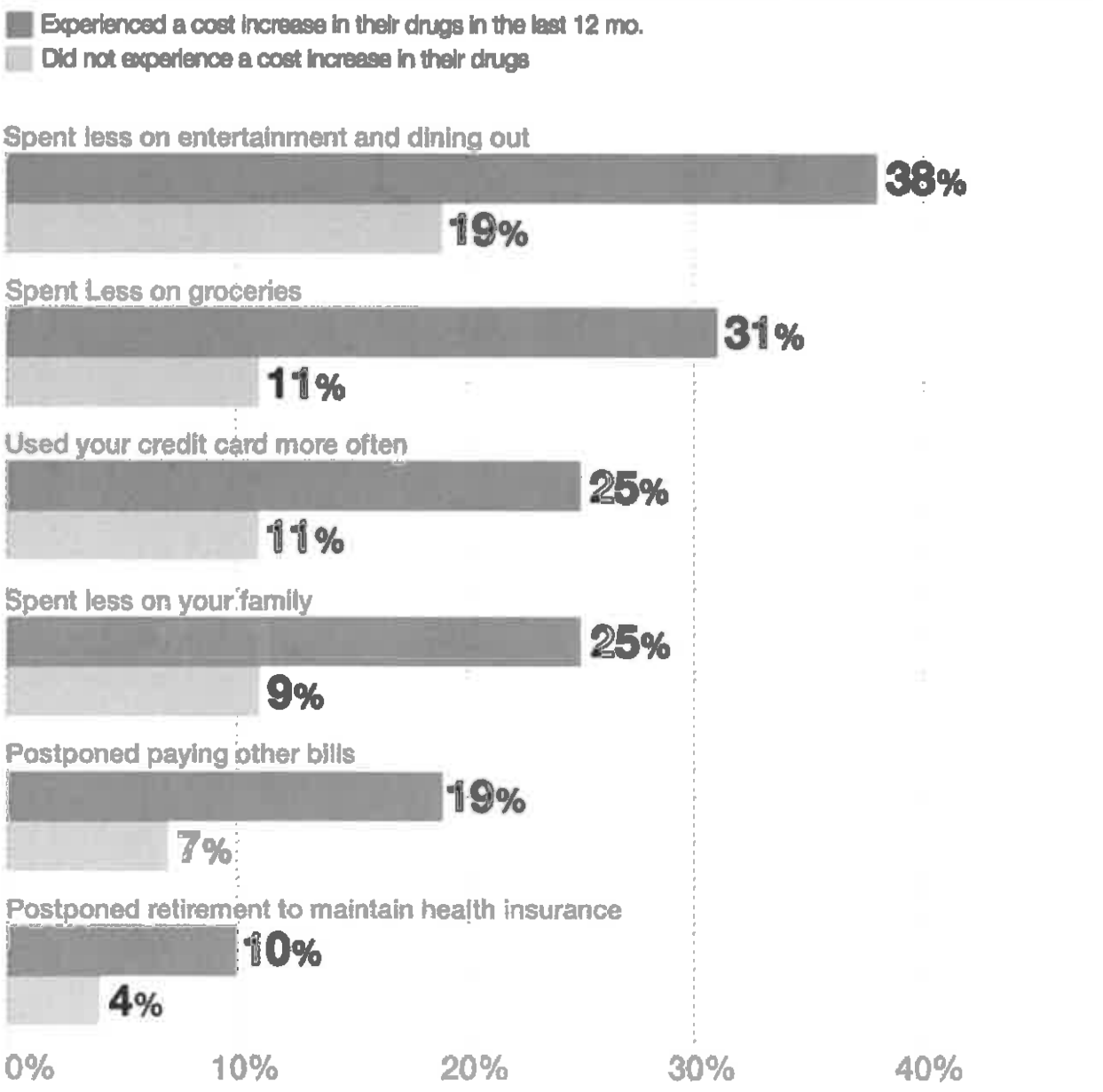
"Even as more patients have health insurance coverage, many more are facing high pharmacy deductibles and rising out-of-pocket costs, and other barriers to care, putting their ability to stay on needed therapy at risk," says Holly Campbell, a representative at PhRMA, an industry association that represents pharmaceutical manufacturers.

"If there's one treatment and there's no alternative and no competition, then that's where the challenge is," says Matt Eyles, executive vice president of policy and regulatory affairs at America's Health Insurance Plans (AHIP), a national trade organization for the insurance industry.

The first step in attempting to correct prices for the consumer good is to understand and acknowledge how we got to this moment. Here, a closer look at the reasons drug costs are ballooning:

WHEN DRUG PRICES RISE, QUALITY OF LIFE GOES DOWN

Consumer Reports Best Buy Drugs conducted a nationally representative telephone poll of 4,015 adult Americans in March 2016. We found that 45 percent of people regularly take a prescription drug and on average take between four and five medications. To afford those, people made adjustments in household spending (see light blue bar below). But for the three in 10 people (29 percent) who reported that they paid more money out of pocket for at least one of their drugs over the prior 12 months, the budget crunch was more dramatic (see darker blue bar).



Source: Consumer Reports Best Buy Drugs Tracking Poll 7, conducted March 10-27, 2016
* Percentages won't add up to 100 because people were able to report multiple actions taken

Reason 1: Drug Companies Can Charge Whatever Price They Want

Nothing protected Condon from the price increases she experienced. That's because for Medicare and commercial health plans, no government body—including the Federal Trade Commission, the Food and Drug Administration, and the Centers for Medicare & Medicaid Services—has rules or laws that dictate or restrict the price a pharmaceutical company can set for a drug. And in most cases, there's nothing that restricts how much a company can raise that price. Here's an example: Last year, on the same day that Valeant Pharmaceuticals purchased the rights to lifesaving heart drug Isuprel (isoproterenol) and blood pressure medication Nitropress (nitroprusside), the company jacked up the prices. A single dose of Isuprel rose from $180 to $1,472, and Nitropress went from $215 to $1,346. The company also purchased Cuprimine (penicillamine)—a drug used to treat Wilson's disease, a rare genetic disorder—and upped its price from $8.88 to $262 per capsule. In all three cases, the drugs had no generic equivalents available, so Valeant was able to corner the market with a built-in base of customers.

"Valeant raised the price of these drugs after an analysis of their actual value," says company representative Laurie Little.

These huge increases have drawn congressional attention because the U.S. government is the largest purchaser of drugs in the country for programs including Medicare and Medicaid, as well as for veterans and the military. Spending more money on drugs because of price increases can mean more taxpayer dollars are used than originally budgeted—something Congress must manage. Last fall, Sens. Susan Collins, R-Maine, and Claire McCaskill, D-Mo., launched a large-scale investigation into sudden and aggressive price increases by four drugmakers, including Turing and Valeant, requesting that the companies turn over documentation to justify the hikes. And earlier this year, Rep. Cummings held a similar congressional hearing, releasing reams of internal memos to the public that detailed the profit goals that companies like Turing were trying to reach by setting the price hikes.

Stephen Lederer, a spokesman for Turing, said the company's pricing for Daraprim "reflected its clinical value." He notes that the company also funded access programs so that a person's insurance co-pays would amount to $10 and provided the drug free to certain disadvantaged patients.

Price manipulations aren't limited to small pharmaceutical firms: Major firms raked in an additional $25.6 billion (gross) in 2015 simply by raising prices on their brand-name drugs, according to a recent report by the IMS. The firm estimates that figure to grow to $155 billion over the next five years.

How do drug companies explain high prices and price hikes? Says Campbell on behalf of PhRMA: "There are many factors that go into a price of a medicine." Those include the drug's "clinical merits"—how well it works, Campbell notes, and whether it reduces other healthcare costs, for example, such as reducing the need for surgery or other types of medical care.

More on High Drug Prices

- Doctors and Rx Prices: Ending the Silence
- Medicare Patients Struggle With Prescription Prices
- As Drug Prices Increase, Quality of Life Goes Down
- Solving the Problem of High Drug Costs
- Battling High Prescription Drug Prices

But other considerations may factor into how a drug's value is determined. For example, in the U.K., a centralized advisory board calculates the value of a medication by taking into account a drug's efficacy, safety, and total benefits to the healthcare system and to society at large. In the U.S., no such central advisory board exists; we effectively leave it up to industry to make that determination instead.

PhRMA's Campbell adds that the price a drug company sets also takes into account expenses involved in research and development. Plus, "revenue from commercially successful medicines is reinvested in research for the next generation of treatments." She points to data from a recent PhRMA survey of member companies that found that companies invested $58.8 billion on research and development in 2015, up 10.3 percent from the prior year.

But American taxpayers already shoulder a substantial burden of those costs. About 38 percent of all basic science research is paid for with tax money through federal and state governments, according to a 2015 study published in the Journal of the American Medical Association.

Moreover, drug companies may spend up to twice as much or more on marketing and promoting their products—including advertising—as they do on research and development. That's according to a new analysis published in the Annals of Internal Medicine in March 2016. Says Wayne Riley, M.D., immediate past president of the American College of Physicians (ACP), one of the largest physician groups in the U.S. and the organization that did the review: "Pharmaceutical companies may price drugs at will, and in truth, it's not clear what that price is based on."

In fact, it would seem that the spending drug companies need to recoup with higher prices is at least partly due to how much is spent on direct-to-consumer advertising. Our review of the 2015 annual reports of 10 of the world's largest drug companies revealed that all spent more on marketing and administration costs than research and development. Ideally, a drug company will spend a substantial portion of its revenue in R&D seeking new discoveries—finding new medical treatments and cures. We found that drug company behemoths Johnson & Johnson and Pfizer spent about 13 percent and 16 percent on R&D, respectively. At the same time, both companies spent about 30 percent of revenue on selling, marketing, and administrative expenses.

The drug industry doesn't play by the same rules as any other market, where exorbitant prices dissuade customers, says Kevin Riggs, M.D., a researcher at the Johns Hopkins University, where he focuses on healthcare costs. "A drug company can increase the price of a product many times over, and people will still buy it because they need it," he says. "At the end of the day, they largely charge whatever the market will bear—and with lifesaving medication, that's a lot."

Reason 2: Insurance Companies Are Also Charging You More

Insurance companies exist, in theory, to protect people from unexpected high costs of healthcare. You pay a monthly premium that goes into large "pool." The

idea is that should you need to draw from that pool to pay for a healthcare expense, it's there for you. In the case of drugs, insurance companies often work with firms called pharmacy benefit managers, or PBMs, that further pool consumers together to negotiate large-volume discounts from drug companies. The idea is that those discounts will ultimately save you money.

The only way left for insurers to provide coverage for a drug but maintain their profit margins is to reduce how much insurance coverage—and thus protection from high prices—they offer to a consumer. That can happen in at least one of four ways: by raising your deductible; by increasing monthly premiums; by increasing your co-pay by putting drugs into more expensive "tiers"; or by making you pay "co-insurance," where you pay a percentage of the medication's cost; usually one-third or more.

"The dramatic increase in prescription drug costs is definitely contributing to a move" to higher insurance deductibles and greater cost sharing with consumers, says Eyles from AHIP, the insurance industry trade organization.

Ten years ago, less than 10 percent of employees with health insurance were enrolled in a plan with a deductible of $1,000 or more. Today, almost half (46 percent) of Americans have those plans, according to research by the Kaiser Family Foundation, a nonprofit organization focused on national health concerns.

Eyles says that insurers have limited leverage with drugmakers, especially when it comes to new and expensive drugs. "There's not a lot we can do other than say we won't cover it, and that's an extreme most plans want to avoid."

But that's exactly what has happened. For its 2016 formulary—the list of drugs covered—Express Scripts, the largest PBM in the U.S., dropped coverage of 80 drugs, including insulins such as Novolin and NovoLog for people with type 1 diabetes, and instead offering coverage for Humulin and Humalog. The company noted in its announcement about the change that it "only exclude[s] medications from our formulary when clinically equivalent alternatives are already covered on our formulary, and only then when those exclusions would result in significant cost savings for our clients and patients."

Reason 3: Old Drugs Are Reformulated as Costly 'New' Drugs

Reinventing old medications is a tactic called evergreening—where companies change or tweak the formula of a drug by, say, combining two older drugs to form a "new" pill. Or they create an extended-release version, or change the delivery method—for example, instead of a tablet or an injectable, the new version is inhaled. When that happens, the federal government may grant the drug company a new patent, which could be worth up to 20 years of protection for its drug, meaning it may not have any generic drug competitors. That can translate to greater revenue for a pharmaceutical company and higher costs for the consumer.

One example is the diabetes drug insulin. The drug is almost 100 years old, and yet no generic version is available in the U.S. That's because drug companies keep changing its formulation and getting new patents for it. Thomas Woodard, 73, of Greensboro, N.C., takes a newer form of insulin called Toujeo. Instead of taking multiple daily injections, his single Toujeo injection lasts about a week. (To be sure, injecting less frequently is more convenient.) Woodard pays about $85 per month for the drug, but there's a problem: When Woodard fills his prescription, the pharmacy and his insurance company will permit him only three vials, which don't entirely cover him for the month, and he can't afford another set of three vials. (They come in a box of three, and pharmacies can't break them up.) So he deals with it another way. "I get to the end of the month, and I just cut back on the number of units I take," Woodard says. That's not a good idea for a person with diabetes like Woodard, whose blood glucose level needs to remain fairly consistent. "Drug companies keep coming out with new insulins, which work better, but the price keeps going up," he says.

Last year 30 products that were reformulations of old drugs hit the market, according to another recent report by the IMS. Says George Slover, senior policy counsel for Consumers Union, the advocacy arm of Consumer Reports: "Evergreening keeps drug prices high for consumers because it makes it harder for lower-cost generic alternatives to enter the market and give consumers a choice."

Reason 4: Generic Drug Shortages Can Trigger Massive Price Increases

Marlene Condon's experience with her medication's skyrocketing price is not an isolated event. Overall, prices of generics increased by almost 9 percent between November 2013 and November 2014, according to a 2015 report by Elsevier, a company that supplies information on drug pricing. Some prices remained stable or even dropped. But the cost of certain drugs went up—way up—when they should have stayed the same or even gone down.

"It's those huge price hikes in everyday drugs that are having the greatest impact on consumers," says Riley of the ACP. "Patients who have been taking generics for years are suddenly finding that their medication is unaffordable." In Marlene Condon's case, it's clear what made her generic arthritis drug, hydroxychloroquine, so expensive. First, some background: At least six companies are approved by the FDA to create generic copies of the drug Condon takes, including three of the biggest in the U.S.: Mylan, Sandoz, and Teva. In theory, having so many companies that make the same drug should increase competition and bring the price down. And that's exactly what happened for more than two decades.

But in recent years, several companies have stopped making older generic drugs such as hydroxychloroquine altogether because they said they couldn't make enough profit selling them. For example, Teva, the largest generic drugmaker, told us it stopped making the arthritis drug in 2012 because of "profitability challenges." Another company, West-Ward, ceased production of the drug in 2014.

When fewer companies make a drug, a new problem is created: If there are any hiccups with getting the drug's "raw" ingredients, it can affect the entire supply in the U.S. That's what happened with hydroxychloroquine, according to a representative from Sandoz, a pharmaceutical firm still making the drug. In 2014, a company that supplies the raw ingredient for the drug failed an FDA inspection and temporarily stopped making it—and soon there was a shortage. The two drugmakers that were able to still get the raw material then upped the price.

Condon's arthritis drug is still expensive, and now she finds discount drug coupons online that cut the cost to less than $300. But it's still a hardship.

What can protect us from sudden price hikes on old drugs? Apparently not the FDA. An agency spokesman, Christopher Kelly, told us the "FDA doesn't have a way to control what a company ultimately decides to charge under our present authorities." Kelly notes that the FDA pays particular attention to new generic drug applications from companies that would prevent shortages of medically necessary drugs. But "the pricing and decisions that companies make regarding pricing is an area currently outside FDA purview, and we have no enforcement capability in this area," Kelly notes.

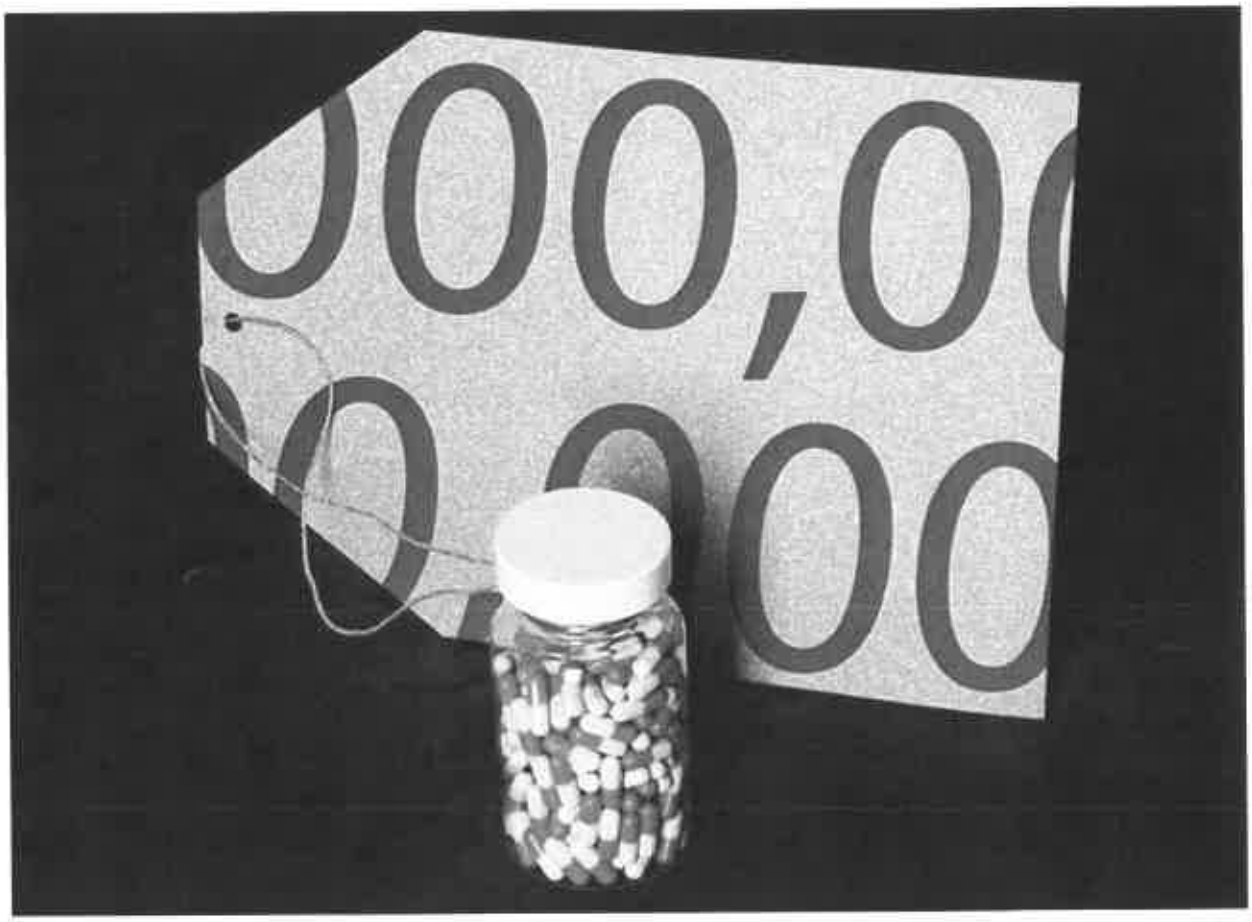


Photo: Fredrick Broden

Reason 5: Specialty Drugs Are Costing All of Us

The rise of super-expensive, so-called specialty drugs is a new threat. Examples include the hepatitis C medications Sovaldi ($84,000 for a 12-week course of treatment) and Harvoni (up to $95,000) that usually target small groups of patients with less common conditions. But their astronomical prices are driving up overall costs for the healthcare system.

Currently, specialty drugs account for less than 1 percent of prescriptions in the U.S. but represent about one-third of total drug spending by consumers, employers, and the government, which all purchase medications, according to a recent report by the Congressional Research Service. And as drug companies invest heavily in those highly profitable products, the IMS estimates that by 2020 very expensive drugs are likely to constitute an even bigger chunk of drug spending.

More than half of the 56 medications approved by the FDA in 2015 were specialty drugs. And more than 900 biologic drugs are currently under development, according to PhRMA. "We're all excited about these new technologies, but it's not at all clear how we as a society are going to pay for it," says Kevin Schulman, M.D., a professor of medicine and business administration at Duke University, where he is also director of the Center for Clinical and Genetic Economics and an associate director of the Duke Clinical Research Institute.

One thing is clear: Consumers' costs will rise. Most Medicare prescription plans require patients to pay one-third or more of the costs of specialty drugs. And consumers still face higher insurance premiums and deductibles, says Eyles of AHIP. "The dramatic growth in this part of the marketplace is unsustainable," he says. "Health plans just can't absorb those costs indefinitely without making adjustments to premiums and benefits."

Unfortunately, we can't always count on competition among drugmakers to drive down prices, says Riggs from Johns Hopkins. Many specialty drugs are biologics, medications that start out as a living organism derived from animals or humans, or from microorganisms, such as bacteria or yeast. That makes them much more difficult to copy than conventional drugs.

To date, the FDA has approved only two "biosimilar" drugs, essentially versions of already existing biologics. Even as those drugs trickle onto the market, Riggs says he's skeptical that biosimilar drugs would substantially lower prices; estimates predict price reductions between 20 and 40 percent, compared with about 80 percent for traditional generics.

What the Government Can Do

Consumers are looking to the government to take action to control drug prices. In our CR Best Buy Drugs poll, 77 percent of people taking a medication said the government should allow more generics onto the market sooner; 74 percent want the government to pressure drug companies to charge less. Seventy-nine percent say insurers should pressure pharmaceutical companies to lower drug prices; 81 percent said consumers should do the same.

More specific steps that could help control costs include asking the government to:

- **Set a limit on out-of-pocket costs.** That would ensure that consumers have some protection against very high costs or sudden large spikes in prices. For example, last year California enacted a law so that a consumer won't pay more than $250 for a single prescription drug per month, or $500 for certain high-deductible plans.
- **Approve more generic versions of common drugs.** Currently, 4,300 generic drug applications await an FDA decision. The agency says it's working to review new applications within 15 months.
- **Allow limited importation of drugs from legitimate Canadian and European sources, which currently is illegal under U.S. law.** The ability to import drugs from countries that have a regulatory system similar to that of the U.S. could alleviate shortages or moderate prices.
- **Use government's existing "march-in" rights.** It works like this: If there is a problem with the public's access to a drug (a supply shortage or an exorbitant price), and if a drug was developed using taxpayer money, the Department of Health and Human Services has the right to force the company to allow another manufacturer to make generic versions that are cheaper for the consumer.

What Drug Companies Can Do

The most obvious help pharmaceutical makers can provide is to charge less—or at least slow the pace of price increases. There is a precedent: Rising drug prices in the 1990s led to public outcry and congressional hearings. And fearing price controls, nine drug companies, led by Merck, made a pledge to keep price increases at or below increases in inflation.

"Pharma has a right to make a profit," says Riley of the ACP, but it also has a "moral obligation" to be transparent about its pricing because it benefits greatly from government-funded research. "The American taxpayer has been providing the venture capital to fund their products," he says. "The public deserves to realize a return on that investment in the form of medications they can afford." But pharmaceutical industry representatives think the focus on price alone is misguided and threatens "to squander our opportunity to usher in the next wave of medical progress," says Campbell at PhRMA.

States are starting to fight back. This past June, Vermont passed the first legislation in the U.S. that requires drug companies to justify high costs and price increases, and to calculate the financial effect on insurance premiums with a select set of drugs. California is currently considering a similar bill.

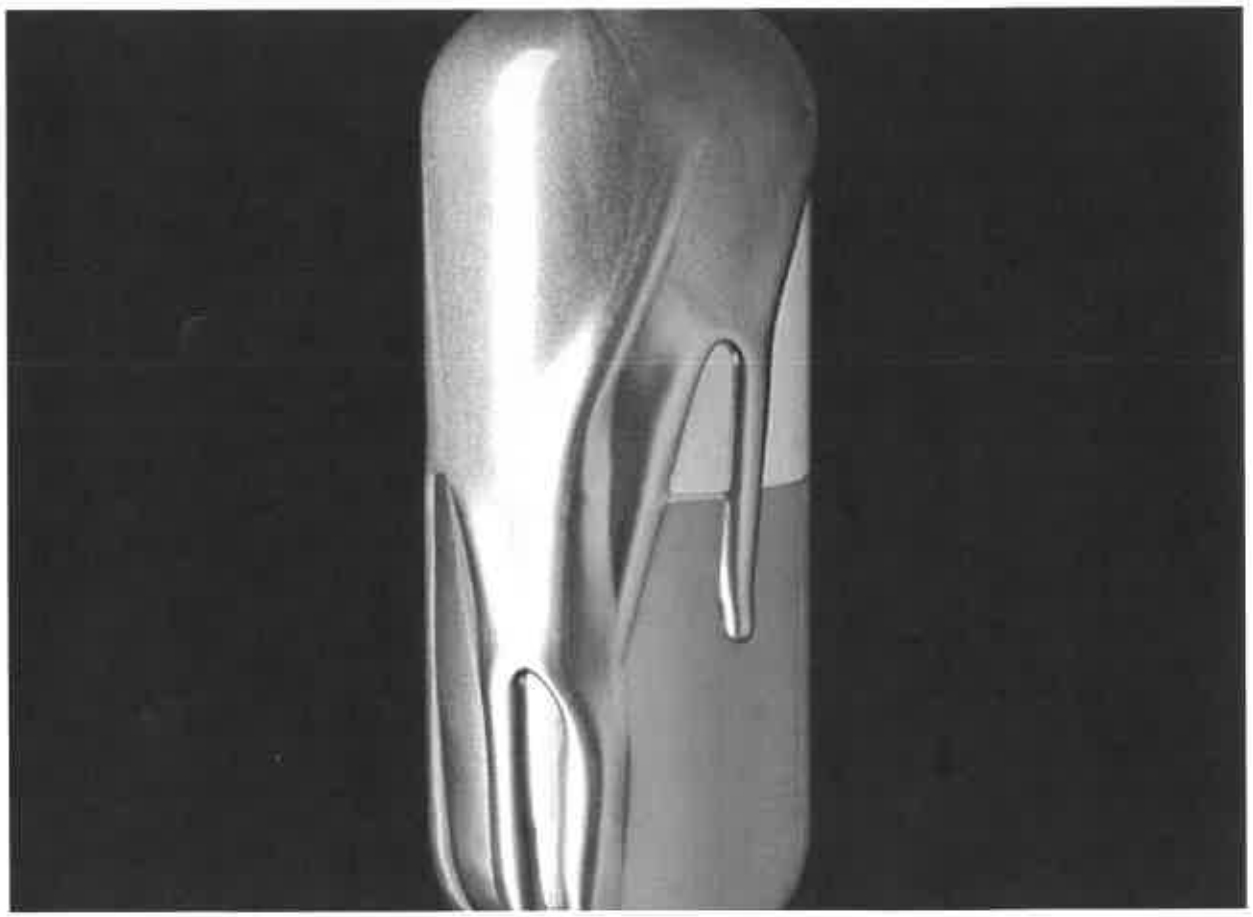


Photo: Fredrick Broden

What Consumers Can Do

Although much of drug pricing is out of consumers' hands, consider these tips to find the best deals at the pharmacy:

- **Talk to your doctor about the cost of the drug she is prescribing.** For less expensive alternatives, ask about generics, which can cost up to 90 percent less. Your doctor might consider "therapeutic substitution"—a different drug that works as well. If your insurance drops or reduces coverage of a drug, your doctor can also help by appealing to your insurance company for an exception to cover the drug anyway. The administrative process for filing the exception is different with each insurance company and can take a few weeks before a decision is made.
- **Shop around and negotiate.** Consumer Reports' secret shoppers have found that retail drug prices can vary widely, even within the same ZIP code. Our shoppers also found that asking, "Is this your lowest price?" could get you further discounts.
- **Check online.** If you pay out of pocket, check GoodRx to learn a drug's "fair price." You can also fill a prescription with a low-cost online pharmacy based in the U.S., such as HealthWarehouse.com. Be careful of fraudulent websites: Use only an online retailer that operates within the U.S. and displays the VIPPS symbol to show that it's a Verified Internet Pharmacy Practice Site.
- **Choose a plan that covers the medications you need.** Compare plans during your open-enrollment period because coverage may change from year to year. Keep in mind that high-deductible plans have lower premiums but require you to pay a larger chunk of your drug costs.

Consumer Reports Is Working to Lower Drug Costs

You are outraged by rising drug costs, and we've listened. Because we do not accept money from the pharmaceutical industry, we can call it like it is. If a drug is too risky or a poor value, we are not afraid to say so. We want your voice to be heard by industry and government. We are advocating for a range of evidence-based solutions for lowering consumers' out-of-pocket costs, ensuring access to essential medicines, and getting better value for our country's prescription-drug

spending—without sacrificing safety or effectiveness. See ConsumerReports.org/drugprices for more.

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